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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| In re: COPAXONE ANTITRUST LITIGATION | : | **Master Docket No. 2:22-cv-1232 (JXN/JSA)** |
| This Document Relates To: | : | **Oral Argument Requested** |
| Direct Purchaser Class Action | : | *Electronically Filed* |

**BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS**

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## INTRODUCTION

Defendants Teva Pharmaceuticals Industries Ltd., Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales & Marketing, Inc. (collectively, "Teva") developed Copaxone as an innovative therapy for patients suffering from relapsing forms of multiple sclerosis ("MS"), the most common cause of neurological disability in young adults. The active ingredient of Copaxone (glatiramer acetate, or "GA") is exceptionally complex, and the way it works to treat MS is not fully understood. Unsurprisingly, it took several years before the U.S. Food and Drug Administration ("FDA") approved generic versions of Copaxone, as generic manufacturers had to satisfy the agency's strict standards for establishing product sameness and bioequivalence. But since generic entry, competition has been vigorous. Indeed, the Complaint alleges that, in order to compete with generic manufacturers, Teva offered rebates and discounts at multiple points in the drug distribution chain—to companies that manage prescription-drug benefits, to specialty pharmacies that dispense the drugs, and to patients to lower their out-of-pocket costs. Class Action Complaint ¶¶ 147-56, 171 (ECF No. 2) ("Compl.").

Even so, generic competitors gained significant traction in a short period of time. According to the Complaint, Teva's market share dropped by nearly 40% between 2015 and 2019, and with further declines since. Compl. ¶¶ 191, 217. Meanwhile, Teva's revenue for Copaxone fell by more than 66% between October

2017 and January 2019, and the net price for Copaxone dropped by more than 40% during the same period. *See* Comm. on Oversight & Reform, U.S. House of Representatives, *Drug Pricing Investigation: Teva-Copaxone* 3, 42, figs. 2, 7 (Sept. 2020) ("House Rept.").[1]

Plaintiffs[2] are assignees of companies that purchased Copaxone directly from Teva after June 18, 2015, and they purport to represent a putative class of direct purchasers of Copaxone. Compl. ¶¶ 13-18, 192-203. In contrast to an earlier lawsuit brought by one of Teva's competitors, Plaintiffs do not allege they were injured by (supposedly) delayed generic competition. Instead, their claims only challenge Teva's alleged conduct ***after*** generic entry, and rest on allegations that Teva's efforts to compete with generic products violated Section 2 of the Sherman Act and the Racketeering Influenced and Corrupt Organizations Act ("RICO"). *Id*. ¶¶ 232-62. Both sets of claims are fundamentally flawed and should be dismissed.

Sherman Act: The Complaint fails to plausibly allege a threshold requirement of a monopolization claim: that Teva exercised monopoly power after generic entry. To the contrary, even assuming that the relevant product market is limited to GA

[1] The Court may consider the House Report because it is cited in the Complaint, and Plaintiffs rely on it to support their claims. *See* Compl. ¶¶ 3-5, 91; *Jones v. Intelli-Check, Inc.*, 274 F. Supp. 2d 615, 626 (D.N.J. 2003) ("courts may consider matters of public record that are relied upon or cited in the complaint").

[2] FWK Holdings, LLC; KPH Healthcare Services, Inc. d/b/a Kinney Drugs, Inc.; Meijer, Inc., and Meijer Distribution, Inc.

products, as Plaintiffs allege, the Complaint shows that the two generic entrants—both major pharmaceutical companies—have won a significant (and growing) share of the market. Moreover, Teva did not (and could not have) relied on its market position to retain Copaxone market share. As the Complaint alleges, Teva competes with generic manufacturers by offering numerous discounts and rebates—conduct that is inconsistent with monopoly power to "control prices and exclude competition." *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co. ("Doryx")*, 838 F.3d 421, 434 (3d Cir. 2016) (citation omitted).

The Complaint also fails to allege that Teva engaged in anticompetitive conduct. Plaintiffs mischaracterize Teva's efforts to compete (*e.g.*, by entering into rebate contracts, introducing new dosages of Copaxone, and offering patients copay support) as antitrust violations. But stripped of conclusory labels, these allegations merely describe vigorous, legitimate competition by Teva. Plaintiffs' real grievance is that Teva ***successfully*** competed with generic GA products, resulting in some doctors, patients, and other actors in the drug-distribution chain choosing Copaxone. But nothing in the Sherman Act required Teva to cede the market to generic competitors without fighting back: "it's perfectly lawful for a competitor to flex its economic muscle with vigor, imagination, devotion, and ingenuity, and act with sharp elbows—as businesses often do." *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 507 F. Supp. 3d 1289, 1363 (D. Kan. 2020)

(citation, brackets, and quotation marks omitted).

RICO: Plaintiffs' RICO claim is based exclusively on allegations that Teva donated to charitable foundations that provide copay support to Medicare patients who were prescribed either brand or generic GA. Plaintiffs allege that Teva conspired with certain charities and specialty pharmacies to funnel Teva's charitable donations exclusively to patients who were prescribed brand Copaxone. This RICO claim fails at multiple steps.

First, the Complaint fails to allege any underlying "predicate" offense that could support a RICO claim. Plaintiffs try to repackage allegations from a separate lawsuit claiming that Teva's charitable donations violated the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b). But the AKS is not within the exhaustive list of laws that can support a RICO claim, 18 U.S.C. § 1961(1), and Plaintiffs' efforts to identify a viable RICO predicate fall short. Plaintiffs invoke mail and wire fraud, but the Complaint's cursory allegations fall far short of the pleading standard, as they vaguely reference unspecified misrepresentations, made at unspecified times, by unspecified entities, to unspecified "health care purchasers." Compl. ¶ 259. The Complaint also invokes the Travel Act, 18 U.S.C. § 1952, but does not even identify a specific Travel Act offense, much less plead facts to support it.

Second, the Complaint fails to plausibly allege proximate causation. In RICO cases, proximate cause "requires 'some direct relation between the injury asserted

and the injurious conduct alleged,'" which generally does not allow recovery for injuries "beyond the first step" in the causal chain. *Hemi Grp., LLC v. City of N.Y., N.Y.*, 559 U.S. 1, 9 (2010) (citation omitted). Yet the Complaint does not identify any "direct" connection between Teva's alleged donations or misrepresentations and Plaintiffs' alleged overpayments for Copaxone, much less that Plaintiffs' alleged injury is only one step removed from any alleged RICO violations. To the contrary, the Complaint alleges that Plaintiffs' purported injury derives from numerous other factors, including Teva's efforts to compete with generic manufacturers, that are ***not*** a basis for Plaintiffs' RICO claim. Moreover, Plaintiffs' claims are derivative of harm allegedly suffered by the federal government from anti-kickback violations, further illustrating the disconnect between the alleged violations and Plaintiffs' injury.

Third, the RICO claim is untimely. At least a year before the March 8, 2018 accrual date, multiple news reports and other public sources, including a public regulatory filing by Teva, put Plaintiffs on notice that charitable foundations offering copay support to Medicare patients were being investigated for possible anti-kickback violations, and that pharmaceutical company donors to these charities (including Teva) were subjects of investigation. Nevertheless, Plaintiffs do not allege that they took any steps to investigate potential violations. Because Plaintiffs should have discovered the basis for their RICO claim more than four years before

they filed suit, it is time barred.

## BACKGROUND

### I. The Prescription Drug Market.

A number of entities are involved in getting prescription drugs that have been approved by the FDA to patients. Typically, drug manufacturers sell drugs directly to wholesalers, who then sell the drugs to pharmacies. *In re Insulin Pricing Litig.*, 2019 WL 643709, at *2 (D.N.J. Feb. 15, 2019). The pharmacy then sells the drugs to patients and is reimbursed for the cost of the drug by the patient's health insurance provider. Compl. ¶ 82.

Pharmacy Benefit Managers ("PBMs") operate in the middle of the distribution chain for prescription drugs, Compl. ¶¶ 81-84, "serv[ing] as intermediaries between pharmaceutical manufacturers and pharmacies on the one hand … and health benefit providers (*e.g.*, insurers, self-insured entities, health maintenance organizations, and public and private health plans) on the other," *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 298 (1st Cir. 2005). PBMs manage prescription drug benefits on behalf of "health insurance companies, self-funded plans, large companies, and governmental entities." Compl. ¶ 81. In this role, PBMs negotiate with drug manufacturers and pharmacies for rebates and discounts paid to the PBM's clients. *Pharm. Care Mgmt.*, 429 F.3d at 298.

PBMs also generate formularies for their payor-clients, which are lists of

prescription drugs covered by the payor's healthcare plan. Compl. ¶ 82. "[T]hrough their control of formularies," PBMs "have a prominent role in determining what drugs will be accessible to patients and at what cost." *Id.* ¶ 84. If a prescribed drug is not on a PBM's formulary for a specific payor, the patient's health plan generally will not cover the drug and the patient will be responsible for the full cost. *Id.* ¶ 82. Consequently, drug manufacturers compete to have their drugs included on a PBM's formulary, including by offering the PBM rebates and discounts. *Id.* ¶ 84. The PBM market is highly concentrated, with the three largest PBMs accounting for more than 75% of the market. *Id.* ¶ 83. This "tremendous market power" gives PBMs leverage in negotiations and enables PBMs "to demand concessions from the manufacturers," including "volume discounts and rebates." *Pharm. Care Mgmt.*, 429 F.3d at 298.

State law also plays a role in determining whether a patient's prescription will be filled with the original FDA-approved "brand" drug or a later approved "generic" version of that drug. Most states have enacted "[a]utomatic generic substitution" laws, which generally either require or allow pharmacists to dispense a generic drug, even if the prescription identifies the brand drug. Compl. ¶¶ 141, 157; *see* Nat'l Conf. of State Legislatures, *Prescription Drug Resource Center* (May 3, 2019).[3] But states also typically authorize pharmacists to dispense the brand drug, "even though

[3] https://www.ncsl.org/portals/1/documents/health/Generic_Drug_Substitution_Laws_32193.pdf.

the generic drug has been approved by the FDA," where the prescription lists the brand drug and specifies that it should be "Dispense[d] as Written" ("DAW"). Compl. ¶ 157; *see also* Nat'l Conf. of State Legislatures, *supra*.

## II. FDA Approves Copaxone And Generic Products.

Copaxone is used to treat patients with relapsing forms of MS. Compl. ¶¶ 86-87. Teva first received approval from the FDA to market Copaxone in December 1996, in 20 mg/vial form, and in February 2002 the FDA approved Copaxone 20 mg for daily injection. *Id*. ¶ 88. Unlike typical small-molecule drugs comprised of simple chemical compounds, Copaxone's active ingredient—glatiramer acetate—is not a single molecular entity; it is composed of a heterogenous mixture of millions of distinct synthetic polypeptides of varying lengths, sequences, and molecular weights. *See* FDA, Letter Denying Citizen Petition, at 9-10 (Apr. 16, 2015).[4] Due to these complexities, the drug's therapeutically active components have yet to be identified. *Id*.

In 2013, Teva sought FDA approval to market Copaxone in a 40 mg dosage to be administered three times a week (rather than daily), which the FDA granted in January 2014. Compl. ¶ 89. By offering "less [frequent] injection[s]," the three-times-a-week regimen afforded Copaxone patients a "more convenien[t]" treatment option and let them choose an injection regimen best suited to their situations. *Id*.

[4] https://www.regulations.gov/document/FDA-2015-P-1050-0012.

¶ 129. Teva began selling the 40 mg product upon receiving FDA approval, but it never removed (or announced any plan to remove) Copaxone 20 mg, which remains on the market.[5] *See id*. ¶ 10 (alleging "Copaxone 20 mg purchases … through the present"); *see also* House Rept., *supra*, at 1, 2.

Two drug manufacturers have secured approval to market generic versions of Copaxone: Mylan Pharmaceuticals, Inc., and Sandoz, Inc. Compl. ¶¶ 92, 97. (Other generic manufacturers have submitted ANDAs for Copaxone 40 mg, but none has yet received FDA approval. *See* Compl. ¶ 101.) Mylan "is one of the world's leading generic and specialty pharmaceutical companies with over 20,000 employees in its family of companies." *Eli Lilly & Co. v. Mylan Pharms., Inc.*, 96 F. Supp. 3d 824, 828 (S.D. Ind. 2015). Sandoz is likewise a multi-billion dollar company with significant experience selling generic drugs.[6] In April 2015, FDA approved Sandoz's application to market a 20 mg version of Copaxone. Compl. ¶ 94. Then, in October 2017, FDA approved Mylan's applications to market both 20 mg and 40 mg GA products. *Id*. ¶ 99. Later, in February 2018, FDA also approved Sandoz's application to market a 40 mg GA product. *Id*. ¶ 96.

When these generic competitors entered the market, they "took a portion of

[5] Teva, *Copaxone Dosing*, www.copaxone.com/about-copaxone/dosage-information (accessed Apr. 5, 2022).

[6] Novartis, *Annual Report* 36 (2017), https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2017-en.pdf (accessed May 15, 2022).

brand Copaxone's unit sales." Compl. ¶ 206. Following Mylan's approval in October 2017, Teva's revenue for Copaxone plunged by almost 50% in just four months and by more than 66% within two years of generic entry. *See* pp. 19-20, *infra*. The net price for Copaxone also dropped rapidly (by more than 40% between October 2017 and January 2019). *See* pp. 20-21, *infra*. Unsurprisingly, Teva's share of the "Copaxone market" declined substantially, too. *Compare* Compl. ¶ 217 (alleging that Teva had 100% market share as of June 2015), *with id*. ¶ 119 (alleging that Teva retained "a majority" (*i.e.*, 50.1% or more) of the Copaxone market for an unspecified number of years following generic entry).

## III. Plaintiffs Piggyback On A Competitor Suit Against Teva To Challenge Teva's Efforts To Compete With Generic Products.

In June 2021, Mylan sued Teva for violations of Section 2 of the Sherman Act, the Lanham Act, and New Jersey law. Mylan's antitrust claim alleged that Teva filed lawsuits and petitions to the FDA to delay generic approval, and then sought to limit generic uptake after FDA approval. Complaint ¶¶ 101-11, 233-48, *Mylan Pharms. Inc. v. Teva Pharms. Indus. Ltd.*, No. 2:21-cv-13087 (D.N.J. June 29, 2021), ECF No. 1. Mylan's Lanham Act claim relied on allegations that unnamed Teva employees supposedly made unspecified false statements regarding Mylan's generic products to a handful of unnamed doctors to persuade them to prescribe Copaxone DAW. *Id*. ¶¶ 157-62, 249-61.

Nearly eight months after Mylan filed its complaint, Plaintiffs brought this

follow-on, putative class-action lawsuit based on allegations that closely mirror those underlying Mylan's lawsuit in several respects. Like Mylan, Plaintiffs allege that Teva violated Section 2 of the Sherman Act by competing vigorously with generic manufacturers to retain market share. Compl. ¶¶ 232-51. For example, Plaintiffs allege that Teva's introduction and promotion of Copaxone 40 mg was an effort to shift patients and doctors to that dosage to avoid generic competition, *id.* ¶¶ 120-44, and that Teva entered into "exclusionary" contracts with PBMs and specialty pharmacies to favor Copaxone over generic GA, *id.* ¶¶ 145-56. The Complaint also parrots Mylan's allegations that Teva made false statements about Mylan's generic product to patients and doctors to convince them to request Copaxone and write prescriptions for Copaxone DAW. *Id.* ¶¶ 157-69. Plaintiffs rely entirely on Mylan's complaint for these allegations, without any indication of an independent investigation. *Id.* ¶¶ 161, 164, 226. In addition, Plaintiffs join Mylan in pressing claims premised on Teva's alleged violation of the Anti-Kickback Statute for the manner in which Teva made donations to charitable foundations to offer copay assistance for MS patients on Medicare. *Id.* ¶¶ 174-82.

But Plaintiffs' claims differ from Mylan's in several respects, even as their Complaint repeats the same basic factual allegations. Most notably, although Plaintiffs devote several pages of their Complaint to reprising Mylan's attacks on Teva's patent suits and agency citizen petitions, they disclaim any theory of antitrust

liability premised on those allegations. *See* Compl. ¶¶ 85, 102-16 (referring to such allegations as "Background Facts"). Instead, Plaintiffs base their claims only on Teva's alleged conduct "following generic entry in June 2015." *Id.* ¶¶ 85, 119-91.[7]

While Plaintiffs' claims are narrower than Mylan's in disclaiming a generic-delay theory, they are broader in three respects. First, Plaintiffs not only allege that Teva's charitable donations to support Medicare patient copays violate the Sherman Act, but they also assert a claim under RICO that is premised on the same alleged conduct. Compl. ¶¶ 252-63. Second, whereas Mylan disavowed any challenge to the ubiquitous practice of copay assistance for patients on private commercial insurance, Plaintiffs allege that Teva's provision of direct-to-patient discounts are anticompetitive. *Id.* ¶¶ 183-87. Third, even though Plaintiffs filed suit after Mylan, they try to claim a longer damages period by alleging that Teva "fraudulent[ly] conceal[ed]" its unlawful conduct. *Id.* ¶¶ 221-31. In doing so, Plaintiffs fail to identify any affirmative misstatements by Teva on which they relied in delaying their suit, nor do they allege that they undertook any steps to investigate their claims.

[7] Teva explained in its pending motion to dismiss Mylan's complaint why allegations regarding its lawsuits and petitions to the FDA do not support antitrust liability. *See* Br. in Supp. of Defs.' Mot. to Dismiss and Mot. to Strike at 18-29, *Mylan Pharms. Inc. v. Teva Pharms. Indus. Ltd.*, No. 2:21-cv-13087 (D.N.J. Mar. 28, 2022), ECF No. 55 ("Teva (Mylan) Br."); Reply Br. in Supp. of Defs.' Motion to Dismiss and Mot. to Strike at 6-13, *Mylan Pharms. Inc. v. Teva Pharms. Indus. Ltd.*, No. 2:21-cv-13087 (D.N.J. Mar. 28, 2022), ECF No. 57 ("Teva (Mylan) Reply Br."). Because Plaintiffs disclaim reliance on these allegations, Teva will not address them here.

## LEGAL STANDARD

To survive a motion to dismiss, a complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[B]ald assertions" and "[l]egal conclusions masquerading as factual conclusions will not suffice." *Anspach ex rel. Anspach v. City of Phila., Dep't of Pub. Health*, 503 F.3d 256, 260 (3d Cir. 2007) (citations omitted). Given "the unusually high cost of discovery in antitrust cases" that can "push cost-conscious defendants to settle even anemic cases," courts should apply pleading requirements rigorously to avoid the time and "potentially enormous expense" associated with litigating "largely groundless claim[s]." *Twombly*, 550 U.S. at 558-59 (citations omitted). This same concern "is just 'as applicable to a RICO case, which resembles an antitrust case in point of complexity and the availability of punitive damages and of attorneys' fees to the successful plaintiff.'" *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 370 (3d Cir. 2010) (citation omitted). Thus, RICO defendants "should not be put to the expense of big-case discovery on the basis of a threadbare claim." *Id*. (citation omitted).

## ARGUMENT

### I. The Complaint Fails To Plausibly Allege A Section 2 Claim.

To state a claim for monopolization under Section 2, a plaintiff must allege "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or

development as a consequence of a superior product, business acumen, or historic accident." *Doryx*, 838 F.3d at 433 (citation omitted). "A monopolist willfully acquires or maintains monopoly power when it competes on some basis other than the merits." *LePage's Inc. v. 3M*, 324 F.3d 141, 147 (3d Cir. 2003).

To plead a Section 2 claim, it is not enough to ask "whether the defendant has engaged in unfair or predatory tactics." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 459 (1993) (quotation marks omitted). "Even an act of pure malice by one business competitor against another does not, without more, state a claim under the federal antitrust laws[.]" *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 225 (1993). Instead, an antitrust plaintiff must identify "conduct which unfairly tends to destroy competition itself." *Spectrum Sports, Inc.*, 506 U.S. at 458. These principles hold true in cases involving alleged monopolists. It "is in the interest of competition to permit dominant firms to engage in vigorous competition, including price competition," *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 116 (1986) (citation omitted), as this is necessary "[t]o safeguard the incentive to innovate," *Verizon Commc'ns Inc. v. Law Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004). Thus, although "the possession of monopoly power" is a necessary requirement for a Section 2 monopolization claim, it is not sufficient; it must be accompanied by "an element of anticompetitive conduct." *Id*.

### A. The Complaint Fails To Plausibly Allege That Teva Possessed Monopoly Power During The Relevant Period.

Plaintiffs expressly limit their antitrust claims to Teva's alleged conduct "[f]ollowing generic entry"—*i.e.*, ***after*** it faced rapidly accelerating competition from rivals who market generic versions of Copaxone. Compl. ¶ 119; *see also id.* ¶ 192 (defining class period to begin on June 18, 2015, when FDA approved Sandoz's product). Plaintiffs have not plausibly alleged that Teva exercises monopoly power in the face of generic competition from Mylan and Sandoz—two well-established, multi-billion dollar companies with ample resources to compete.

To establish monopoly power, Plaintiffs must provide either "direct evidence of supracompetitive prices and restricted output," or indirect evidence of both "a dominant share in a relevant market" and "significant 'entry barriers'" that "protect that market." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007) (citation omitted). Here, Plaintiffs have not plausibly alleged that Teva maintained market power following generic entry under either framework. Far from identifying direct evidence of Teva's monopoly power through the ability to control prices and exclude competition, the Complaint alleges that Teva relied on substantial rebates and discounts to compete after generic entry, *e.g.*, Compl. ¶¶ 146, 152—"allegations [that] ***undercut*** an inference that [Teva] has an excess share" of the market. *LLM Bar Exam, LLC v. Barbri, Inc.*, 271 F. Supp. 3d 547, 583-84 (S.D.N.Y. 2017) (emphasis added), *aff'd*, 922 F.3d 136 (2d Cir. 2019). Likewise, the Complaint, and

the documents it incorporates by reference, reveal that Teva's revenue for Copaxone and corresponding market share have steadily dropped since Sandoz and Mylan entered the market, making it impossible to infer that Teva is a monopolist. *See* pp. 19-21, *infra*.

Courts have dismissed similarly deficient allegations of monopoly power. *See, e.g., Blix Inc. v. Apple, Inc.*, 2020 WL 7027494, at *6 (D. Del. Nov. 30, 2020); *LLM Bar Exam*, 271 F. Supp. 3d at 583-84; *Rio Grande Royalty Co. v. Energy Transfer Partners, L.P.*, 786 F. Supp. 2d 1202, 1212, 1215 (S.D. Tex. 2009). This Court should follow suit.

**1. The Complaint Does Not Plausibly Allege Direct Evidence That Can Establish Monopoly Power.**

"[D]irect evidence of monopoly power … is only 'rarely available.'" *Doryx*, 838 F.3d at 434 (citation omitted). To rely on direct evidence, the plaintiff must plausibly allege (and ultimately show) "***both***" that the defendant "'restricted output'" and "had an 'abnormally high price-cost margin.'" *Id*. (emphasis added and citations omitted); *see also Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 464 (1992) (describing monopoly power as "the ability of a single seller to raise price and restrict output" (citation omitted)). The Complaint does not allege either one.

First, there are ***no*** allegations that Teva restricted output of Copaxone, either before or after generic entry. That omission alone prevents Plaintiffs from plausibly alleging direct evidence of market power, as it leaves no basis to infer that allegedly

high prices were caused by market power rather than other legitimate factors. *See, e.g.*, *Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1475 (9th Cir. 1997) (holding that evidence of high prices "[w]ith no accompanying showing of restricted output" failed to establish monopoly power); *In re Intuniv Antitrust Litig.*, 496 F. Supp. 3d 639, 660 (D. Mass. 2020) ("Absent any evidence of restricted output, ... evidence of high margins is insufficient direct evidence ***as a matter of law*** to demonstrate market power." (emphasis added, citation omitted)); *Meijer, Inc. v. Barr Pharms., Inc.*, 572 F. Supp. 2d 38, 55 (D.D.C. 2008) (explaining that market power could not be established with direct evidence absent "a showing that Warner Chilcott's higher prices were the result of restricted output"); *In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 683 (D.N.J. 2005) (similar).

Second, Plaintiffs have not plausibly alleged that Teva's prices for Copaxone were supracompetitive during the relevant period. Notably, Plaintiffs' "[d]irect evidence" allegations concern Teva's supposed market power ***before*** generic entry. Compl. ¶ 206. Indeed, Plaintiffs ***concede*** that Teva "lost Copaxone sales in response to pricing of … AP-rated generic Copaxone." *Id.* In addition, the Complaint provides no basis to infer that Teva's price-cost margin for Copaxone was "abnormally high" at any point. *Doryx*, 838 F.3d at 434 (citation omitted). Plaintiffs merely allege that the "per-unit manufacturing cost for Copaxone" was substantially lower than the "net price of the drug." Compl. ¶ 206. But that narrow focus on the

"per-unit manufacturing cost" is the wrong measure, because it fails to account for the high "initial fixed costs" that brand manufacturers incur, such as "research, development, and the cost of being the first to gain FDA drug approval." *Remeron*, 367 F. Supp. 2d at 468.[8] The Complaint simply ignores this issue.

**2. The Complaint Does Not Plausibly Allege That Indirect Evidence Can Establish Monopoly Power.**

Absent plausible allegations of direct evidence of monopoly power, Plaintiffs must rely on allegations of indirect evidence based on Teva's market share and "[o]ther germane factors," such as its "ability to maintain market share," "the size and strength of competing firms," and the "ability of consumers to substitute comparable goods." *FTC v. AbbVie Inc.*, 976 F.3d 327, 371-72 (3d Cir. 2020) (citation omitted). Once again, Plaintiffs' allegations fall short.[9]

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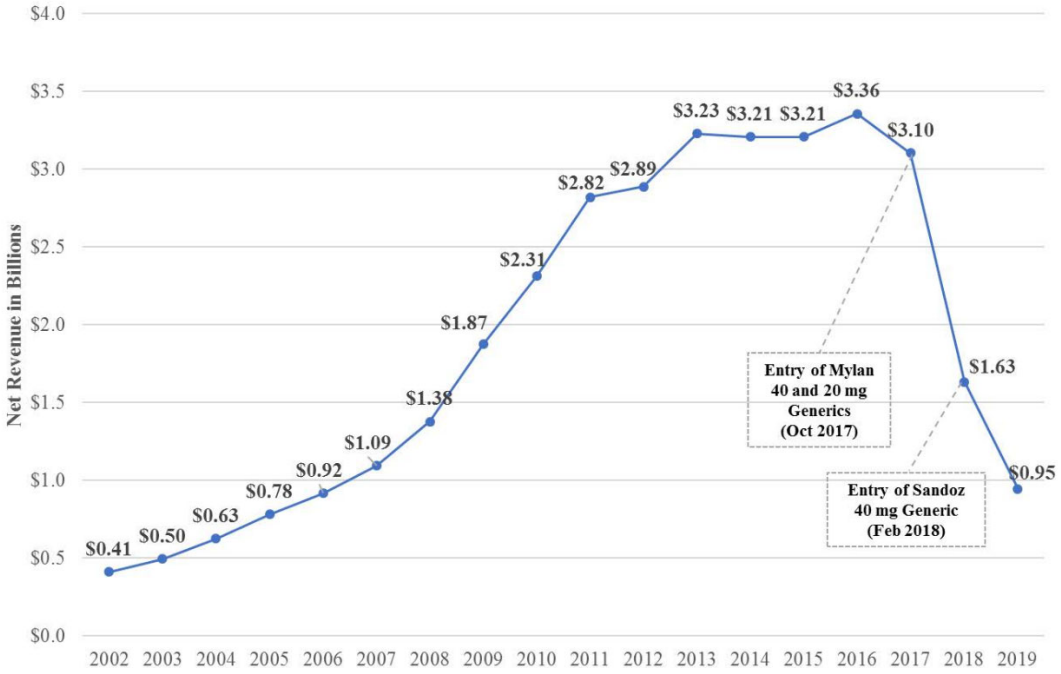
[8] *See also, e.g.*, *Intuniv*, 496 F. Supp. 3d at 659 ("Courts have noted … that, '[i]n the market for a product with high fixed costs,' such as a brand pharmaceutical product, 'evidence that prices routinely exceed marginal costs may not necessarily be evidence that prices are supracompetitive, because even competitive prices may exceed marginal cost.'" (quoting *In re Asacol Antitrust Litig.*, 323 F.R.D. 451, 484 (D. Mass. 2017))); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *11 (D. Mass. Jan. 25, 2018) (similar, and further noting that generic firms' gross margins also substantially exceed their marginal costs); *Garnica v. HomeTeam Pest Def., Inc.*, 230 F. Supp. 3d 1155, 1159 (N.D. Cal. 2017) ("inferring market power from gross margins is a dicey proposition").

[9] Teva disagrees with Plaintiffs' market definition (Compl. ¶ 215), which improperly excludes from the product market other brand medications for MS that compete with Copaxone. *See, e.g.*, *Doryx*, 838 F.3d at 436 (holding that product market "was much broader" than brand product and its generic equivalents). But for purposes of this motion to dismiss, Teva accepts *arguendo* the Complaint's artificially narrow market definition.

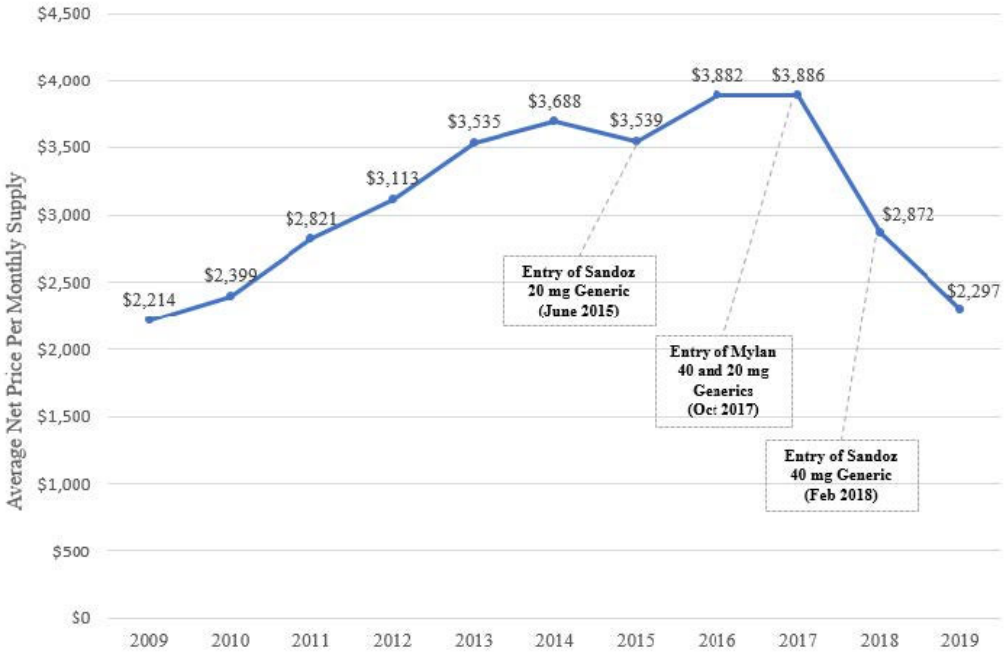
"Although there is no fixed percentage market share that conclusively resolves whether monopoly power exists, the Supreme Court has never found a party with less than 75% market share to have monopoly power." *Kolon Indus. Inc. v. E.I. DuPont de Nemours & Co.*, 748 F.3d 160, 174 (4th Cir. 2014). As the Third Circuit has explained, it typically takes a market share of "significantly greater than 55 percent" before a court may infer market power. *AbbVie Inc.*, 976 F.3d at 371; *see also Kolon*, 748 F.3d at 174 (market share of less than 60% weighs "heavily" against an inference of monopoly power). Moreover, "'[i]n evaluating monopoly power," it is not the percentage alone that counts, but whether the defendant is able "to ***maintain*** market share" over time. *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 188-89 (3d Cir. 2005) (citation omitted)); *see also It's My Party, Inc. v. Live Nation, Inc.*, 88 F. Supp. 3d 475, 500 (D. Md. 2015) (addressing "durability" of market power and concluding that monopoly power was absent where the defendant's share had ranged from 60%-66%), *aff'd*, 811 F.3d 676 (4th Cir. 2016). Here, the Complaint's allegations, combined with the documents the Complaint incorporates by reference, undermine any inference that Teva maintained durable monopoly power after generic entry.

The House Report on which Plaintiffs rely shows that Teva's Copaxone revenue fell off a cliff after Mylan's October 2017 launch, dropping by almost half

in just four months and decreasing by more than two-thirds in less than two years. *See* House Rept., *supra*, at 3, fig. 2.




The net price for Copaxone also dropped precipitously, declining by more than 40% between October 2017 and January 2019. *Id*. at 42, fig. 7.




Given these shifts, the Complaint's allegations about Teva's market share after generic entry do not support a plausible inference of monopoly power. Plaintiffs allege that "as of June 2019, Teva still held more than 64% of the market," and that "in November 2019," it "held 63% of the market." Compl. ¶¶ 189, 191. But those percentages are lower than what courts typically require to infer monopoly power, *see* p. 19, *supra*, and any such inference is further undermined because Teva's market share has consistently trended downward. Indeed, it is telling that Plaintiffs do not allege Teva's ***current*** market share, and instead merely allege vaguely that Teva has "maintain[ed] a majority of the Copaxone market for years following generic entry." Compl. ¶ 119; *see id.* ¶ 217. That allegation is "too conclusory to plausibly establish market power in ***any*** context." *FTC v. Facebook,*

*Inc.*, 560 F. Supp. 3d 1, 18 (D.D.C. 2021) (collecting decisions). Moreover, even if this conclusory allegation were credited, it is inadequate on its face, because "it is well-established that 50% market share or just over is insufficient to establish monopoly power," particularly when that share has declined. *Synthes, Inc. v. Emerge Med., Inc.*, 2012 WL 4473228, at *11 n.5 (E.D. Pa. Sept. 28, 2012)*; see also Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 112 (3d Cir. 1992) (50% market share insufficient to create "a dangerous probability" of monopolization).

Other factors confirm that Teva has not maintained the power "to control prices and exclude competition." *Doryx*, 838 F.3d at 434 (citation omitted). In particular, the "size and strength of competing firms" strongly undercuts any inference of monopoly power. *AbbVie Inc.*, 976 F.3d at 371 (citation omitted). Mylan and Sandoz are not upstarts: they are multi-billion dollar companies with ample resources to compete in the GA market. *See* p. 9, *supra*. The "presence of [these] other large competitors in the market undermines [Plaintiffs'] claim." *Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 580 (S.D.N.Y. 2011); *see also Foam Supplies, Inc. v. Dow Chem. Co.*, 2007 WL 4210354, at *5 (E.D. Mo. Nov. 27, 2007) ("The fact that Dow has large competitors as opposed to numerous very small competitors indicates that Dow lacks monopoly power or the ability to obtain such power."). Moreover, Mylan and Sandoz enjoy a significant competitive advantage over Teva, as they benefit from state automatic substitution laws that let

them secure sales without needing to invest in advertising. Compl. ¶ 157.

Perhaps most significantly, the Complaint's allegations show that generic competition has been effective. Far from being able to control prices by virtue of its market position, Teva responded to generic competition by offering discounts and rebates to PBMs and specialty pharmacies in order to avoid losing Copaxone sales, Compl. ¶¶ 146, 152, 206—actions that are "entirely inconsistent with the exercise of market power." *Com. Data Servers, Inc. v. Int'l Bus. Mach. Corp.*, 262 F. Supp. 2d 50, 74 (S.D.N.Y. 2003); *see also Ryko Mfg. Co. v. Eden Servs.*, 823 F.2d 1215, 1232 (8th Cir. 1987) (stating that "direct evidence of competitive pressure," shown by, *inter alia*, "the entry of new competitors" or "the product's price sensitivity," "indicates a lack of market power"); *LLM Bar Exam*, 271 F. Supp. 3d at 584 (dismissing Section 2 claim for failure to plausibly allege market power, and noting inconsistency of the plaintiff's allegations that "an alleged monopolist" had to "discount" its product "to compete").

In the end, Plaintiffs' claim reduces to displeasure that Teva did better after generic entry than is "typical" for a brand manufacturer. Compl. ¶¶ 119, 190. But the Sherman Act is not offended when a brand manufacturer competes with generics, including by offering pricing terms that some purchasers find more attractive than generic alternatives.

### B. The Complaint Does Not Plausibly Allege That Teva Violated Section 2 Through Exclusive Dealing (Count I).

The Complaint alleges that Teva "entered into" two types of "exclusionary agreements with PBMs and specialty pharmacies" that "severely restricted market access for generic Copaxone and substantially lessened competition." Compl. ¶ 145; *see also id*. ¶¶ 232-41. *First*, the Complaint alleges that Teva entered into agreements with an unnamed number of PBMs, under which the PBMs agreed "to exclude generic Copaxone from their formularies" in exchange for rebates. *Id*. ¶¶ 5, 119, 145-47. *Second*, the Complaint alleges that Teva paid unnamed specialty pharmacies rebates for the pharmacies to dispense Copaxone, regardless of whether the prescription specifically called for the branded product. *Id*. ¶¶ 150-56. Stripped of pejorative labels, these allegations describe legitimate price competition by Teva.

#### 1. The Alleged PBM And Specialty Pharmacy Contracts Are Subject To The Price-Cost Test.

The Complaint's allegations regarding the alleged PBM and specialty pharmacy contracts boil down to an objection that Teva competed based on price by using "rebates" to "induce" PBMs and specialty pharmacies to "agree[]" to the contracts with Teva. Compl. ¶¶ 146, 150, 152. Because the use of above-cost price incentives is inherently procompetitive, these allegations cannot sustain a claim.

"[C]utting prices in order to increase business often is the very essence of competition." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594

(1986). As a result, the Third Circuit applies the "price-cost" test where a defendant's above-cost prices are the "clearly predominant mechanism of exclusion." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 275 (3d Cir. 2012). Under that test, a plaintiff's challenge to a defendant's rebates fails if the defendant's prices remain "above-cost." *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 409 (3d Cir. 2016). Importantly, "a plaintiff's characterization of its claim as an exclusive dealing claim does not take the price-cost test off the table." *ZF Meritor, LLC*, 696 F.3d at 275. Instead, the price-cost test "extend[s] to above-cost discounting or rebate programs," so long as "pricing itself" "operated as the exclusionary tool." *Id*. at 274-75.

Plaintiffs' claim cannot survive the price-cost test because the Complaint never alleges that Teva's rebating practices resulted in below-cost pricing—indeed, it alleges the opposite. *E.g.*, Compl. ¶ 206. Moreover, there is no question this test should apply because price is the "predominant"—indeed, the only—"mechanism of exclusion" alleged as to these two contracting arrangements. *ZF Meritor, LLC*, 696 F.3d at 275. In particular, the Complaint alleges that Teva "pa[id] rebates" to "induce PBMs and specialty pharmacies" to enter into the alleged contracts. Compl. ¶¶ 146, 150, 152. But a firm employing "loyalty discount[s] or rebate[s] to compete with similar products" is exactly the context in which the price-cost test applies. *Eisai, Inc.*, 821 F.3d at 409; *see ZF Meritor, LLC*, 696 F.3d at 275 (price-cost test

"extend[s] to above-cost discounting or rebate programs").

Seeking to evade the price-cost test, the Complaint insists that Teva's rebates were not "the predominant mechanism of exclusion" because Teva supposedly "leveraged its monopoly power to block generic Copaxone from formularies and to ban generic Copaxone from being shipped." Compl. ¶ 146. But Plaintiffs' legal conclusion must be ignored, *see Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), and their colorful (and conclusory) language is just word play.

The Complaint's allegation that Teva "block[ed]" generic GA from some formularies fails, because the only "mechanism of exclusion" alleged is that Teva allegedly offered more attractive rebates in exchange for exclusivity. Compl. ¶¶ 147-49. In other words, Teva secured exclusivity with some PBMs by offering them price concessions, which is precisely the conduct that the price-cost test categorically protects. *See Eisai, Inc.*, 821 F.3d at 409. Equally flawed is Plaintiffs' rhetoric about Teva allegedly "ban[ning] generic Copaxone from being shipped." Compl. ¶ 146. Teva is not a government regulator that can "ban" a competitor's product. Instead, Plaintiffs seem to mean only that Teva provided specialty pharmacies with "an additional rebate" for filling prescriptions for GA with Copaxone rather than generic alternatives. *Id.* ¶ 152. Once again, alleged exclusion through above-cost rebates and discounts is not cognizable under the antitrust laws.

Merely relabeling pricing discounts as "kickbacks"[10] or competitor "ban[s]," *id.* ¶¶ 146, 154, does not change the analysis, *see ZF Meritor, LLC*, 696 F.3d at 275 (recognizing that a plaintiff's characterization of claims is not controlling).

**2. Plaintiffs' Exclusive Dealing Claim Also Fails Under The Rule Of Reason.**

Even if the price-cost test does not apply, the Complaint fails to plausibly plead that the alleged exclusive contracts are unlawful under the rule of reason. "Exclusive dealing agreements are often entered into for entirely procompetitive reasons," *ZF Meritor, LLC*, 696 F.3d at 270, and "in many circumstances … may be highly efficient … and pose no competitive threat at all," *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 76 (3d Cir. 2010) (citation omitted). Thus, to state a claim, a plaintiff must plausibly allege that an agreement "will foreclose competition in such a substantial share of the relevant market so as to adversely affect competition." *ZF Meritor, LLC*, 696 F.3d at 271. To evaluate market foreclosure, courts consider (1) the contracts' duration, (2) whether they are

[10] The Complaint alleges in cursory fashion that Teva's alleged rebates to PBMs and specialty pharmacies violated the federal Anti-Kickback Statute. Compl. ¶ 153. As explained below, Plaintiffs cannot rely on the AKS to support an antitrust claim. *See* pp. 46-47, *infra*. Moreover, Plaintiffs have not plausibly alleged that Teva's alleged contracts with PBMs and specialty pharmacies are subject to the AKS. That law applies only to payments made in connection with a "Federal health care program," 42 U.S.C. § 1320a-7b(b)(2)(A), but the Complaint does not allege facts suggesting that Teva's rebates were paid to PBMs or specialty pharmacies acting on behalf of a federal health care program, Compl. ¶¶ 145-56.

terminable at-will, and (3) whether "the dominant firm engaged in coercive behavior." *Id*. at 271-72.

The Complaint does not plausibly allege that the PBM or specialty pharmacy agreements foreclosed a substantial share of the market. Indeed, although the Complaint alleges that there are multiple PBMs and specialty pharmacies in the market with varying market shares, Compl. ¶¶ 81-83, it does not specify which (or how many) PBMs or specialty pharmacies entered contracts with Teva, *id*. ¶¶ 145-56. At most, the Complaint suggests that Teva entered agreements with two PBMs and specialty pharmacies, *id*. ¶ 147, but it does not identify the entities or their market shares—leaving Plaintiffs short of plausibly alleging foreclosure of a substantial portion of the market.[11] *See Dickson v. Microsoft Corp.*, 309 F.3d 193, 208-09, 211 (4th Cir. 2002) (holding that the complaint did not plausibly allege substantial market foreclosure when it did not include "allegation[s] regarding [the defendants'] power or share in the [relevant] market"); *Eastman v. Quest Diagnostics Inc.*, 724 F. App'x 556, 558-59 (9th Cir. 2018) (holding that the complaint failed to plausibly allege substantial market foreclosure because, among other reasons, it "did not allege the market shares" of contracting entities).

The Complaint also fails to allege facts regarding the duration of the alleged

[11] The Complaint's allegations that the contracts "severely restricted market access" and "foreclosed" generic competition, Compl. ¶¶ 145, 154, are legal conclusions that must be ignored, *see Iqbal*, 556 U.S. at 678.

contracts or their terminability, which is significant because "short-term agreements … present little threat to competition." *ZF Meritor, LLC*, 696 F.3d at 286. This omission is unsurprising, as it is well known that contracts between drug manufacturers and PBMs are renegotiated "regularly, typically on an annual basis," and are easy for PBMs to terminate. *EpiPen Antitrust Litig.*, 507 F. Supp. 3d at 1354-55 (rejecting antirust claim challenging such agreements since "[p]ayors regularly invoked the contracts' termination provisions" and "frequently renegotiated their rebate percentages," and collecting similar cases). Plaintiffs allege no facts to suggest that Teva's agreements with PBMs and PBM-owned specialty pharmacies were any more restrictive. That omission leaves Plaintiffs unable to plausibly allege substantial market foreclosure and compels dismissal of their claim for exclusive dealing. *See Shire US, Inc. v. Allergan, Inc.*, 375 F. Supp. 3d 538, 558 (D.N.J. 2019) (dismissing claims challenging alleged exclusive dealing contract between drug company and health plan that restricted formulary access for competitors where the contracts at issue were for one-year and open to competitive bidding on an annual basis).

Finally, the Complaint does not plausibly allege that Teva engaged in coercive behavior when entering into the challenged PBM and specialty pharmacy agreements. Plaintiffs assert that Teva "leveraged its monopoly power," Compl. ¶ 146, but they do not allege ***facts*** to back up that accusation. To the contrary, the

Complaint recognizes that "[t]he PBM market is highly concentrated," giving PBMs significant leverage in their negotiations with drug manufacturers to "control … formularies and pharmacy networks" and thus to "determin[e] what drugs will be accessible to patients and at what cost." *Id.* ¶¶ 83-84. The Complaint further contradicts any inference of coercion by reproducing a document stating that Teva offered a "range" of potential contracts with PBMs and specialty pharmacies, including contracts "allowing access to Copaxone 40 mg alongside generic[.]" *Id.* ¶ 155. All that remains is Plaintiffs' allegation that Teva's rebates "induce[d] PBMs and specialty pharmacies to accept the exclusionary contracts," *id.* ¶¶ 146, 150, but "it's not coercion for a payor to agree to accept a lower price," *EpiPen Antitrust Litig.*, 507 F. Supp. 3d at 1349-50 (rejecting exclusive dealing claim where the defendant "offered payors a range of rebates conditioned on various formulary placement" and "[i]n some instances … offered payors greater rebates if they agreed to exclusivity" but the "only consequence for payors who rejected [the] exclusive offers was losing access to greater discounts").

Ultimately, the Complaint suggests that Teva engaged in anticompetitive conduct because its contracts were designed "not to compete, but to 'Defend Against Generic Erosion.'" Compl. ¶ 155. But successful competition by a brand manufacturer will by definition reduce "generic erosion." Plaintiffs' real objection is that Teva competed at all. The Complaint conspicuously lacks any allegations as

to why Sandoz and Mylan could not "match" (or beat) Teva's rebates and discounts, and thereby compete on the merits. *Eisai, Inc.*, 821 F.3d at 409.[12] Pricing strategies do not become exclusionary merely by being attractive to customers.

### C. The Complaint Fails To Plausibly Plead An "Overarching Monopolization Scheme" Claim (Count II).

Plaintiffs try to make up for the deficiencies in their exclusive-dealing claim by mixing that claim with a series of other allegedly wrongful conduct as part of an "overarching monopolization" claim. Compl. ¶¶ 157-87, 242-51. None of these additional allegations supports a Section 2 claim independently, and they cannot do so collectively. At bottom, Plaintiffs' grievance across all its allegations is that Teva vigorously competed to maintain its market share, but such competition is exactly what the antitrust laws encourage.

#### 1. Plaintiffs' Allegations Regarding Teva's Introduction Of A New 40 mg Product Do Not Support A Section 2 Claim.

The Complaint alleges that Teva "thwarted generic competition" by introducing Copaxone 40 mg and seeking to transition patients to that product before

[12] The Complaint gestures in this direction by alleging that "a 60% price cut by Mylan had only a muted impact on Teva's market share." Compl. ¶¶ 188-89. The Complaint does not, however, allege any facts suggesting the significance of Mylan's alleged 60% reduction, such as a comparison of the net price of Copaxone with generic alternatives, even after the alleged 60% reduction. Nor does the Complaint allege whether Mylan could have reduced prices further and still remained profitable. *See NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 452 (6th Cir. 2007) (en banc) (explaining that a company has no right under the antitrust laws to preserve its desired profit margin).

generic 20 mg GA entered the market. Compl. ¶¶ 120-44. These "product-hop" allegations fail to plausibly establish anticompetitive conduct.

"[C]ourts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes." *United States v. Microsoft Corp.*, 253 F.3d 34, 65 (D.C. Cir. 2001) (en banc). After all, "[p]roduct innovation generally benefits consumers" who gain access to new options that may better fit their needs. *N.Y. ex rel. Schneiderman v. Actavis PLC ("Namenda")*, 787 F.3d 638, 652 (2d Cir. 2015). Here, for example, Teva's 40 mg product provided patients with a less frequent treatment regimen, requiring only three injections per week rather than daily injections. Compl. ¶ 89. Because taking Copaxone involves a precise injection protocol, requiring active patient support and training, Teva's three-times-a-week regimen expanded patients' choice and offered them a "more convenien[t]" treatment option. *Id*. ¶¶ 89, 129, 162, 164, 171. And while Plaintiffs try to impugn Teva's motives and question the "significan[ce]" of the 40mg product's "improvement in convenience," *id*. ¶ 121, "simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014). Rather, new product introduction can give rise to antitrust concerns ***only*** when "***combine[d]*** … with some other conduct" that "coerce[s] consumers" and "impede[s] competition."

*Namenda*, 787 F.3d at 654 (emphasis added); *see also Doryx*, 838 F.3d at 440. The Complaint fails to allege any such coercion resulting from Teva's introduction of Copaxone 40 mg.

*a. Plaintiffs Fail To Plausibly Allege A "Hard Switch."*

Plaintiffs' product-hop allegations fail right out of the gate because they do not allege that Teva engaged in a "hard switch." Courts adjudicating product-hop claims have drawn "an important distinction between hard and soft switches." *In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 269 (D. Mass. 2017). In a "hard switch," the brand withdraws its old product from the market before generic entry to "force[] patients" to shift to a new patent-protected product, whereas in a "soft switch" the brand tries "to persuade patients and their doctors to switch" from the old formulation to a new one "while both [are] on the market." *Namenda*, 787 F.3d at 654. A soft switch "do[es] not have the same anticompetitive result[s]" as a hard switch "because the market can determine whether one product is superior to another … so long as the free choice of consumers is preserved." *Asacol*, 233 F. Supp. 3d at 269 (citation and quotation marks omitted).

The Complaint alleges that Teva engaged in a "product switch," Compl. ¶ 141, but it does ***not*** allege that Teva withdrew Copaxone 20 mg from the market upon introducing the 40 mg product—or ever. In fact, Copaxone 20 mg remains on the market and continues to be prescribed to this day. *See* p. 9, *supra*. Thus, Teva's

introduction and promotion of Copaxone 40 mg did not "eliminate the free choice of consumers," Compl. ¶ 142; instead, by keeping "both products on the market," Teva "preserved" "consumer choice," *Asacol*, 233 F. Supp. 3d at 269.[13] Nor did Teva's actions "den[y] generic manufacturers a fair opportunity to compete using state substitution laws." Compl. ¶ 141. By leaving the 20 mg dosage on the market, Teva left generic manufacturers "free[] to compete," including by encouraging PBMs, patients, and physicians to stay with the 20 mg dosage. *See Asacol*, 233 F. Supp. 3d at 269.

Courts have consistently dismissed Section 2 claims, like the one presented here, that do not allege a hard switch. *See, e.g., id.*; *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2015 WL 5458570, at *13 (D. Mass. Sept. 16, 2015) (dismissing claim premised on brand's alleged efforts "to shift the market away from doses" of Solodyn "that stood to face generic competition" toward "new strengths" because the brand "continued selling the [le]gacy [s]trengths" for several years); *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 148, 151-52 (D.D.C. 2008) (dismissing claim premised on allegations that AstraZeneca "deliberately switched the market" from Prilosec to Nexium "just as Prilosec's

[13] The Complaint alleges that Teva "planned to 'Discontinue 20mg Financial Programs (Patient Services),'" Compl. ¶¶ 132, 135, but it does not allege that Teva actually did so, or that it even made any public statement on the issue. To the contrary, the Complaint's only basis for this allegation is an "[i]nternal" document that was "not for use in promotion." *Id.* ¶ 135.

patent was about to expire" because AstraZeneca kept both products on the market and therefore had not "eliminat[ed] choices available to the consumer"). This Court should do the same.

Moreover, because Teva preserved consumer choice by making both dosages of Copaxone available to patients, the Complaint's attempts to question the benefits represented by Copaxone 40 mg's three-time-a-week regimen, Compl. ¶¶ 126, 128, are legally irrelevant. "Preference is a matter of individual taste," making it impossible for courts to "determine with any reasonable assurance whether one product is 'superior' to another." *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 (2d Cir. 1979); *see also Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co.*, 2015 WL 1736957, at *15 (E.D. Pa. Apr. 16, 2015) ("doubt[ing] that courts could ever fashion" "an intelligible test of innovation 'sufficiency'") (citation omitted), *aff'd*, *Doryx*, 838 F.3d at 440 ("courts should also be wary … of … turning [themselves] into tribunals over innovation sufficiency"). That is why "simply introducing a new product on the market, whether it is a superior product or not," does not independently "constitute exclusionary conduct." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d at 682. Here, Teva preserved "the free choice of consumers" by leaving the 20 mg product on the market, *Berkey Photo*, 603 F.2d at 287, and inquiries into "Teva's true motivation for bringing Copaxone 40mg to market," Compl. ¶ 121, are thus not

cognizable under the antitrust laws. In any event, at least ***some*** patients must have valued the ability to cut down their weekly Copaxone injections by more than half, and Plaintiffs never allege otherwise.[14] That is enough.

*b. The Complaint Does Not Allege Coercion Absent A "Hard Switch."*

Unable to allege the hard switch that courts have found essential to stating a Section 2 claim, Plaintiffs nonetheless insist that Teva's efforts to shift the market were improperly coercive. Compl. ¶¶ 132-44. But their allegations fail to plausibly allege that Teva engaged in anticompetitive conduct.

The Complaint starts by attacking Teva's prices, alleging that Teva "priced the 40mg product ***lower*** than the 20mg product," which Plaintiffs assert "does not make economic sense." Compl. ¶¶ 133-34, 143. But it is hardly unusual for companies to lower prices to promote a new product. *See* Robert B. Reich, *Toward a New Consumer Protection*, 128 U. Pa. L. Rev. 1, 22 (1979) ("It is often necessary

[14] The Complaint relies on a snippet from a "Teva executive" in 2008 questioning whether an "every other day over once daily" dosage "represent[s] a significant improvement in convenience." Compl. ¶ 126. That statement concerned a different possible dosing regimen than the three-times-a-week regimen that Teva adopted, and it was made before Teva "stud[ied]" whether to pursue a three-times-a-week dosage. *Id*. ¶¶ 126-27. It does not plausibly undermine the obvious consumer benefit from substantially reducing the number of injections, and, in fact, later Teva documents recognize that the company expected the 40mg product to attract patients "aiming at less injection/more convenience." *Id*. ¶ 129. Plaintiffs' remaining allegations as to the alleged lack of "scientific rationale/value" of a three-times-a-week regimen have no relevance to whether that regimen offered consumers a more convenient product. *Id*. ¶ 127.

for sellers to offer new products at a discount … in order to offset consumers' understandable reluctance to sail such uncharted seas."). Moreover, Plaintiffs cannot support their antitrust claim based on Teva ***lowering*** its prices, so long as they remained above-cost. *See* pp. 24-25, *supra*. The Complaint nevertheless tries to buttress its pricing allegations by asserting that Teva took steps to induce "price separation" by "implement[ing] a 9.8% price hike on the 20mg product," Compl. ¶¶ 133-34, but it does not allege that Teva's alleged price increase for Copaxone 20 mg was out of step with normal price increases for that product, *id*. ¶ 91, fig. 1. Indeed, the House Report on which the Complaint relies suggests the exact opposite. *See* House Rept., *supra*, at 2, fig. 1.

The Complaint also alleges that Teva "forced PBMs to add the 40mg product to their formularies" by "conditioning" the payment of "Copaxone 20mg rebates" on doing so. Compl. ¶ 136. Plaintiffs describe this as "tying," *id*. ¶¶ 6, 132, 142, 224, but do not allege improper "tying" within the meaning of antitrust law. "[A] tying arrangement may be defined as an agreement by a party to sell one product … but only on the condition that the buyer also purchases a different (or tied) product …, or at least agrees that he will not purchase that product [or service] from any other supplier." *Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 397 (3d Cir. 2016) (citation omitted). The Complaint does not allege that Teva ***required*** anyone to purchase Copaxone 40 mg (or even to add it to a formulary) in order to

maintain access to Copaxone 20 mg, or that Teva required minimum purchase commitments for Copaxone 40 mg. Instead, Plaintiffs merely allege that Teva offered price incentives (*i.e.*, rebates) to encourage PBMs to include a new product on their formularies. "[T]he threat of a lost discount is a far cry from the anticompetitive conduct" courts have found coercive. *See Eisai, Inc.*, 821 F.3d at 407.

The Complaint nonetheless purports to have identified coercion because "one PBM lost its 2015 rebates for failing to add the 40mg to its formulary" but then "got in line" and "added it" the "following year." Compl. ¶ 136. This allegation conflates improper coercion with legitimate efforts to use price incentives to increase customer choice by encouraging PBMs to offer ***both*** the 20 mg and 40 mg products in their formularies. There is no principle of antitrust law that prioritizes maximizing the leverage of PBMs over consumer access to new medicines.

Finally, the Complaint alleges that Teva "incentivized PBMs to lobby prescribers directly to switch patients from the 20mg to 40mg," and that it also used (and incentivized) its "sales force" to promote Copaxone 40 mg. Compl. ¶¶ 137, 138. But once again, there is nothing anticompetitive about Teva promoting its product to doctors and patients, or with specialty pharmacies doing the same. The antitrust laws do not "prohibit[] market switching through sales persuasion short of false representations or fraud." *Walgreen Co.*, 534 F. Supp. 2d at 152. Indeed, the

Complaint's allegations that Teva "incentivized," "encourage[d]," and "urge[d]" physicians to prescribe Copaxone 40 mg, Compl. ¶¶ 137, 138, are inconsistent with any plausible theory of coercion. And the manner in which Teva structured internal bonuses (*id*. ¶ 139) has no conceivable relevance to whether its promotion of Copaxone 40 mg was coercive.

*c. Plaintiffs' Product-Hop Claim Is Untimely.*

Plaintiffs also cannot rely on Teva's alleged market-shifting efforts to support a Section 2 claim because all of the challenged conduct took place well outside the four-year statute of limitations period. *See* 15 U.S.C. § 15b.

The Complaint was filed on March 8, 2022, making any claim that accrued on or before March 8, 2018 untimely. Plaintiffs allege that Teva's "switch" to Copaxone 40 mg in 2014 harmed them because the only generic on the market at the time—Sandoz's 20 mg generic—could not compete with Copaxone 40 mg. Compl. ¶¶ 140-41. But Mylan's generic 20 mg and 40 mg products were on the market as of October 4, 2017, *id*. ¶ 100—well before the March 8, 2018 accrual date. And Plaintiffs have not plausibly alleged that they suffered any continuing injury from the alleged shift ***after*** Mylan's 40 mg product entered the market. Plaintiffs' challenge to Teva's introduction of Copaxone 40 mg is thus untimely.

**2. Teva's "Dispense As Written" Campaign Was Not Anticompetitive.**

Plaintiffs also seek to support their Section 2 claim with allegations—copied

from Mylan's complaint—that Teva supposedly made "untrue and misleading statements to doctors and patients" to persuade doctors to prescribe Copaxone DAW and patients to request it. Compl. ¶¶ 157-69. These allegations fall far short of plausibly pleading an antitrust claim premised on alleged misstatements.

Multiple circuits "have adopted a presumption that misrepresentations or false statements about a competitor have a de minimis effect on competition." *Duty Free Ams., Inc. v. Estee Lauder Cos., Inc.*, 797 F.3d 1248, 1268-69 (11th Cir. 2015) (collecting cases); *see also, e.g., Retractable Techs., Inc. v. Becton Dickinson & Co.*, 842 F.3d 883, 895 (5th Cir. 2016) ("false advertising alone hardly ever operates in practice to threaten competition"); *Mercatus Grp., LLC v. Lake Forest Hosp.*, 641 F.3d 834, 851 (7th Cir. 2011) ("[E]ven false statements about a competitor serve to set the stage for competition." (citation and quotation marks omitted)). The Third Circuit, too, has held that "false or deceptive statements" may violate the antitrust laws only "in 'rare[ ]' circumstances." *Eisai, Inc.*, 821 F.3d at 407 n.40 (citation omitted). At a minimum, an antitrust plaintiff must plausibly allege that the misrepresentations "induced or were likely to induce reasonable reliance by consumers," and "could not have [been] corrected … by supplying … accurate information." *Id.*

Plaintiffs' misrepresentation theory fails for multiple reasons. To start, the Complaint simply recycles allegations from the "lawsuit recently filed by … Mylan

against Teva" without any indication that Plaintiffs' counsel conducted any independent investigation. Compl. ¶ 161; *see id*. ¶ 164 ("According to Mylan ..."). Given attorneys' "nondelegable responsibility" under Rule 11 to independently investigate a complaint's allegations, *Pavelic & LeFlore v. Marvel Ent. Grp.*, 493 U.S. 120, 126 (1989), courts have rejected efforts to base claims solely on untested allegations from another case, *see, e.g.*, *Attia v. Google LLC*, 2018 WL 2971049, at *15 (N.D. Cal. June 13, 2018); *Geinko v. Padda*, 2002 WL 276236, at *6 (N.D. Ill. Feb. 27, 2002). The Court should likewise reject Plaintiffs' attempted bootstrapping.

In any event, Plaintiffs' borrowed allegations fall short for effectively the same reasons that Mylan's claims fail. *See* Teva (Mylan) Br. 37-42; Teva (Mylan) Reply Br. 19-21. Indeed, the Complaint here is even more vague and conclusory, as it does not attribute any specific false or misleading statements to particular Teva representatives, much less does it describe the circumstances under which any alleged statements were supposedly made. For example, although Mylan's false-statement theory (and, by extension, Plaintiffs' theory) depends on an alleged inconsistency between statements made by Teva and the FDA's approval of Mylan's product, the Complaint does not allege whether Teva's purported statements came before or after that approval. Teva (Mylan) Br. 39. The Complaint also does not allege any factual basis from which to infer that several alleged statements—*e.g.*, that Mylan "did not offer training" "nursing support" or "financial assistance," and

"other" unspecified "untrue statements"—***were actually false***. Compl. ¶¶ 162-64.

Plaintiffs' allegations also suffer from several additional deficiencies that plagued Mylan's complaint, including Plaintiffs' failure to meaningfully account for the sophisticated nature of the target audience for Copaxone advertising: doctors. *See, e.g., Retractable Techs., Inc.*, 842 F.3d at 895 (recognizing that "sophisticated" consumers are more likely to "attach[] little weight to statements and [to] instead regard[] them as biased and self-serving"); *Tate v. Pac. Gas & Elec. Co.*, 230 F. Supp. 2d 1072, 1080 (N.D. Cal. 2002) (similar). Plaintiffs concede that doctors are "sophisticated decisionmakers," but cast aside this issue with a conclusory allegation that doctors still "rely on drug manufacturers" for "information." Compl. ¶ 163. That cursory assertion does not provide a plausible basis to infer that doctors who prescribe Copaxone would blindly accept a drug manufacturer's characterization of its competitor's product.

For similar reasons, Plaintiffs provide no basis to infer that Mylan was unable to "correct[]" the alleged "misstatements" by providing "accurate information." *See Eisai, Inc.*, 821 F.3d at 407 n.40. The Complaint alleges in conclusory fashion that the purported misrepresentations were "difficult if not impossible to neutralize," Compl. ¶ 163, and reproduces a paragraph from Mylan's complaint alleging that "a large number of providers … refused to even talk to … Mylan['s] representatives or argued with them." *Id*. ¶ 162. But the relevant legal question is not whether Mylan

was "successful" in its marketing, but whether the alleged misrepresentations were "susceptible to neutralization." *Am. Pro. Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Pro. Publ'ns, Inc.*, 108 F.3d 1147, 1152 (9th Cir. 1997). For example, the Complaint offers no facts to explain why Mylan could not "correct" alleged misrepresentations about its product's efficacy by pointing to FDA approval. Compl. ¶¶ 36, 99, 162.

Ultimately, Plaintiffs' Complaint (like Mylan's before it) boils down to a criticism of DAW, combined with speculation that Teva's success in driving "Dispense as Written" prescriptions must have resulted from a misinformation campaign. *E.g.*, Compl. ¶¶ 164, 166-67. But DAW messaging is a legitimate way for brand companies to compete—it is how brands can secure sales despite being disadvantaged by state laws that otherwise require or allow a prescription for a brand company's product to be filled with a generic competitor's product. *See id.* ¶ 157. And Plaintiffs' assumption that Teva's DAW success is attributable to lies about competitors is not plausible in light of the "obvious alternative explanation" of brand loyalty. *Twombly*, 550 U.S. at 567-68. Taking a dose of Copaxone is not like swallowing a pill: it involves a precise injection protocol that requires specific injection devices, active patient support, and training. *See* Compl. ¶¶ 89, 162, 164, 171. Given doctors' and patients' decades-long experience with Copaxone, it is unremarkable that many would have been reluctant to alter a tried-and-true treatment

regimen. Thus, the Complaint's copycat allegations fail to provide any plausible basis to infer that Teva's success in convincing doctors to prescribe Copaxone DAW is attributable to a campaign of alleged misrepresentations. *Twombly*, 550 U.S. at 570 (holding that allegations that fail to "nudge[]" a claim "across the line from conceivable to plausible" must be dismissed).

### 3. The Alleged Charitable Contributions And Commercial Copay Support Do Not Support A Section 2 Claim.

The Complaint next takes aim at Teva's efforts to provide copay support to MS patients. The Complaint alleges that Teva violated the Sherman Act by providing copay support to patients on private insurance and by donating to charities that pay the copays of Medicare patients prescribed brand or generic GA. Compl. ¶¶ 170-91.[15] These allegations offer no support for Plaintiffs' Section 2 claim.

#### *a. Teva's Commercial Copay Support Program Is Not Anticompetitive.*

The Complaint alleges in cursory fashion that Teva "ma[de] payments to cover patient copays" and thereby "retained patients on brand Copaxone." Compl. ¶¶ 183, 187. These allegations merely object that Teva helped patients lower their

[15] The Complaint also alleges that "Teva offered patient services, such as free injection devices, to promote patient use of brand Copaxone," which allegedly "provide[d] a forum for connecting patients with the financial aspects of Teva's patient assistance programs." Compl. ¶ 171. The Complaint does not offer any further detail on this alleged conduct or explain how providing "free injection devices" could possibly be anticompetitive.

out-of-pocket costs for Copaxone in order to encourage them to stay with the product. *Id*. ¶¶ 183-87. As noted, above-cost price competition is categorically immune from antitrust scrutiny, so long as price is the "clearly predominant mechanism of exclusion." *ZF Meritor, LLC*, 696 F.3d at 275; *see also* pp. 24-25, *supra*. Co-pay coupons for consumers plainly fall within this framework.

Teva is not aware of a single court that has suggested, much less held, that a copay assistance program violates the antitrust laws. Indeed, copay assistance programs are commonly used by brand manufacturers to compete. *See Am. Fed'n of State, Cnty. & Mun. Emps. Dist. Council 37 Health & Sec. Plan v. Bristol-Myers Squibb Co.*, 948 F. Supp. 2d 338, 343 (S.D.N.Y. 2013) ("co-pay subsidy administration has become a 'cottage industry'"). That is no doubt why Mylan has not alleged that this ubiquitous practice is unlawful. Plaintiffs' real objection is that Teva's copay assistance program was ***successful***, because patients on private insurance stayed with Copaxone, Compl. ¶¶ 185-86, but that is not a basis for treating patient-level discounts as anticompetitive.

*b. Teva's Alleged Charitable Contributions Were Not Anticompetitive.*

Plaintiffs next allege that Teva's charitable contributions violated the Sherman Act by violating an entirely different law: the AKS. Compl. ¶¶ 174-82. In support, Plaintiffs rely on a pending Department of Justice ("DOJ") lawsuit against Teva in which the DOJ has alleged that Teva "paid illegal copay subsidies" to

Copaxone patients on Medicare by "coordinat[ing]" donations to charitable foundations that provide copay support to MS patients "to increase the likelihood that the payments would cover brand Copaxone copays only." *Id*. ¶¶ 175-76. These allegations offer no support for a Section 2 claim.

Plaintiffs' allegations in relation to Medicare copayments suffer from the same fundamental flaw as their commercial copay allegations. Teva disputes Plaintiffs' accusation that any of Teva's contributions to charities violated the AKS. But even accepting Plaintiffs' premise, the Complaint's allegations boil down to a claim that Teva's contributions lowered the out-of-pocket expenses of Copaxone patients and thereby "induced" patients to remain on Copaxone. Compl. ¶ 170. Once again, attempts to win business through discounts "is the very essence of competition," *Phila. Taxi Ass'n, Inc v. Uber Techs., Inc.*, 886 F.3d 332, 340 (3d Cir. 2018) (citation omitted), and cannot support a Section 2 claim, *see* pp. 24-25, *supra*.

The Complaint's allegations that the alleged charitable contributions violate the AKS does not move the antitrust ball. "Even unlawful conduct is 'of no concern to the antitrust laws' unless it produces an anticompetitive effect," *Phila. Taxi Ass'n, Inc.*, 886 F.3d at 340 (citation omitted). Plaintiffs therefore cannot support a Sherman Act claim on the theory that engaging in price competition by lowering out-of-pocket costs for patients violated some other law, *see Wichita Clinic, P.A. v. Columbia/HCA Healthcare Corp.*, 45 F. Supp. 2d 1164, 1192-93 (D. Kan. 1999)

(rejecting claim that a violation of the AKS would "constitute the sort of antitrust injury that would justify a claim under Section 2").

In fact, the existence of a distinct regulatory regime policing "kickbacks" under the AKS counsels strongly against extending the antitrust laws to punish patient discounts. *See Trinko, LLP*, 540 U.S. at 412-13. The AKS provides "a comprehensive bifurcated civil and criminal scheme for addressing fraudulent and abusive payment practices in federal health care programs," and "complex, detailed regulations" have been promulgated to implement the statute's requirements. *PPD Enters., LLC v. Stryker Corp.*, 2017 WL 4950064, at *3 (S.D. Tex. Nov. 1, 2017) (citation omitted). There is no reason to stretch antitrust law to an area subject to its own enforcement regime. That is especially true, as doing so would allow an end-run around Congress's decision to give the Attorney General exclusive authority to enforce the AKS. *See Allstate Ins. Co. v. Linea Latina De Accidentes, Inc.*, 781 F. Supp. 2d 837, 850 (D. Minn. 2011). Other courts have rejected attempts by private plaintiffs to repurpose the Sherman Act to challenge alleged AKS violations.[16] Teva respectfully urges this Court to follow suit.

[16] *See, e.g.*, *Digene Corp. v. Third Wave Techs., Inc.*, 536 F. Supp. 2d 996, 1006 (W.D. Wis. 2008), *aff'd*, 323 F. App'x 902 (Fed. Cir. 2009); *Action Ambulance Serv., Inc. v. Atlanticare Health Servs., Inc.*, 815 F. Supp. 33, 37-38 (D. Mass. 1993).

### 4. Plaintiffs' Defective Theories Of Exclusionary Conduct Do Not Turn Into A Plausible Theory When Combined.

For purposes of Count II of the Complaint, Plaintiffs do not allege that any of the alleged categories of conduct ***independently*** supports a Section 2 claim, but rely instead on their "combined effect." Compl. ¶¶ 188, 248. This theory does not cure the fundamental deficiencies in Plaintiffs' theories of liability.

Plaintiffs will likely invoke the rule that courts should evaluate "the anticompetitive effect of [a defendant's] exclusionary practices considered together." *LePage's Inc.*, 324 F.3d at 162; *accord Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962). But that principle does not help the Plaintiffs here, because before they can aggregate the alleged impact of Teva's conduct, they must first plausibly allege that at least some aspect of Teva's conduct is anticompetitive and exclusionary. "Logically … if none of the alleged conduct is exclusionary or anticompetitive, it cannot collectively violate section 2 of the Sherman Act." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 2017 WL 3967911, at *8 n.10 (E.D. Pa. Sept. 8, 2017).[17]

[17] *See also, e.g.*, *Eatoni Ergonomics, Inc. v. Rsch. in Motion Corp.*, 486 F. App'x 186, 191 (2d Cir. 2012) ("Because these alleged instances of misconduct are not independently anti-competitive, we conclude that they are not cumulatively anti-competitive either."); *City of Anaheim v. S. Cal. Edison Co.*, 955 F.2d 1373, 1376 (9th Cir. 1992) (rejecting "overall wrongdoing" theory based on "a number of perfectly legal acts"); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2015 WL 5458570, at *13 (claim dismissed when none of the alleged conduct was

Moreover, "not all actions of an alleged violator may be properly considered … as ingredients in a 'monopoly broth.'" *Valassis Commc'ns, Inc. v. News Corp.*, 2019 WL 802093, at *10 (S.D.N.Y. Feb. 21, 2019). Relevant here, pricing and contracting activities that are *per se* lawful do not support an "overall scheme" claim, as "the evidence that the practice is anticompetitive is so 'utterly lacking.'" *See Valassis*, 2019 WL 802093, at *10 (citation omitted); *see also* Daniel A. Crane, *Does Monopoly Broth Make Bad Soup?*, 76 Antitrust L.J. 663, 669 (2010) ("above-cost price cutting" and "product-design changes" are "immunized from liability" and do not "become illegal based on their cumulative effect"). Thus, allegations regarding Teva's discounting practices and its decision to launch a new product without a hard switch cannot give rise to antitrust liability. Similarly, Plaintiffs cannot prop up an overall scheme claim by challenging conduct from outside the limitations period. *See, e.g.*, *New York v. Facebook, Inc.*, 549 F. Supp. 3d 6, 45-47 (D.D.C. 2021).

* * * * *

Plaintiffs attack legitimate efforts by Teva to win customers by offering new products and attractive prices in the face of vigorous competition by two major generic manufacturers. Whether viewed independently or collectively, none of

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independently anticompetitive); *Simon & Simon, PC v. Align Tech., Inc.*, 2019 WL 5191068, at *8 (D. Del. Oct. 15, 2019) (same).

Plaintiffs' allegations supports a plausible Section 2 claim.

## II. The Complaint Fails To State A RICO Claim (Count III).

The Complaint alleges that Teva violated RICO, 18 U.S.C. § 1962, based ***exclusively*** on its allegations regarding Teva's alleged donations to charitable foundations that provide copay support to Medicare patients. Compl. ¶¶ 252-63; *see also id*. ¶¶ 170-82. Courts in this District have recognized that "[c]areful scrutiny" of RICO claims "is appropriate because of the 'relative ease with which a plaintiff may mold a RICO pattern from allegations that, upon closer scrutiny, do not support it.'" *Absolute Power Sys., Inc. v. Cummins, Inc.*, 2016 WL 6897782, at *4 (D.N.J. Nov. 23, 2016) (citation omitted). Thus, efforts to repackage unrelated claims into a RICO treble damages action "should be 'flush[ed] out' at early stages of the litigation." *Cedar Swamp Holdings, Inc. v. Zaman*, 487 F. Supp. 2d 444, 449 (S.D.N.Y. 2007) (citation omitted).

Here, Plaintiffs have taken the allegations underlying the DOJ's action against Teva under the AKS—a statute that is not privately enforceable, *see* p. 47, *supra*—and attempted to transform them into a claim for treble damages under RICO. *See* Compl. ¶¶ 174-82, 256. Plaintiffs' efforts to manufacture a RICO claim fall short.

### A. The Complaint Fails To Plausibly Allege A RICO Predicate Act.

To state a RICO claim, a plaintiff must plausibly allege, among other things, that the defendant violated one or more of a lengthy list of state and federal offenses.

*See* 18 U.S.C. §§ 1961, 1962(c); *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d at 362. The Complaint purports to satisfy this "predicate act" requirement by alleging that Teva's charitable contributions violated three laws identified as RICO predicate offenses: (1) 18 U.S.C. § 1341 (mail fraud), (2) 18 U.S.C. § 1343 (wire fraud), and (3) 18 U.S.C. § 1952 (Travel Act). But Plaintiffs do not plausibly allege that Teva's charitable donations violate any of these provisions. Compl. ¶¶ 252-63.

**1. Plaintiffs Fail To Adequately Allege Mail Or Wire Fraud.**

To plead mail or wire fraud, a plaintiff must allege "the existence of a scheme to defraud." *In re Ins. Brokerage Antitrust Litig.*, 2017 WL 3642003, at *6 (D.N.J. Aug. 23, 2017) (citation omitted). A "scheme to defraud," in turn, requires "some sort of fraudulent misrepresentations or omissions reasonably calculated to deceive persons of ordinary prudence and comprehension." *Network Commodities, LLC v. Golondrinas Trading Co., LTD.*, 2013 WL 1352234, at *11 (D.N.J. Apr. 1, 2013) (citation omitted). Importantly, a plaintiff must plead fraud "with particularity" under Fed. R. Civ. P. 9(b), which requires the plaintiff to plead "the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *In re Valent Pharms. Int'l, Inc.*, 2020 WL 9809347, at *22 (D.N.J. Aug. 24, 2020) (quoting *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007)). These rules are designed "to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard

defendants against spurious charges of immoral and fraudulent behavior." *McBride v. Twp. of Wash.*, 2020 WL 3396802, at *5 (D.N.J. June 19, 2020) (citation omitted).

The Complaint fails to plausibly allege fraud even under the ordinary Rule 8 standard, much less under the heightened standard imposed by Rule 9(b). The Complaint repeatedly refers to Teva's sales and charitable contributions as "fraudulent." Compl. ¶¶ 254, 256, 259, 260(e). Such conclusory invocations of the "fraud" label fail basic pleading requirements. *See, e.g.*, *District 1199P Health & Welfare Plan v. Janssen, LP*, 2008 WL 5413105, at *10 (D.N.J. Dec. 23, 2008) ("General allegations, such as fraud … will not satisfy the pleading standard"). Otherwise, the Complaint merely alleges, in the most general terms and in the passive voice, "the transmission of untrue or incomplete statements intended to mislead health care purchasers regarding the existence, amount, and purpose of Teva's Copaxone patient assistance payments." Compl. ¶ 259. This allegation does not identify a single "untrue," "incomplete," or "mislead[ing]" statement by Teva, much less when it was made or any meaningful specifics regarding its content.[18] Nor does the Complaint identify who made any "untrue or incomplete statements" or to whom such statements were made; it merely asserts that unspecified statements were

[18] As noted, the Complaint recycles vague allegations from Mylan's complaint that Teva supposedly made misrepresentations regarding Mylan's product. *See* pp. 39-41, *supra*. But notably, Plaintiffs do not rely on these allegations to support their RICO claim. *See* Compl. ¶¶ 252-63.

"intended to mislead" unspecified "health care purchasers." *Id.*; *see also id.* ¶¶ 170-82, 252-63. That, again, is plainly insufficient. *See Plumbers & Pipefitters Loc. 572 Health & Welfare Fund v. Merck & Co.*, 2014 WL 12621229, at *4 (D.N.J. June 30, 2014) (dismissing RICO claim where the complaint did not identify any specific misrepresentations and "barely hint[ed] at the subject of the misrepresentations").

Plaintiffs have no excuse for being so vague. They are themselves "health care purchasers," Compl. ¶¶ 13-18, 262, so if Teva had made false statements in order to induce sales, Plaintiffs should be able to identify them. *Cf. District 1199P*, 2008 WL 5413105, at *12 (holding that the plaintiffs were not entitled to relaxation of Rule 9(b) standards because they had not alleged that information was in the defendant's "exclusive control" or detailed the plaintiffs' efforts to obtain it) (citing *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272 (3d Cir. 1992)).

If Plaintiffs mean to suggest that subsidizing patient copayments to encourage brand sales is itself "fraudulent[]," Compl. ¶ 256, their theory is legally baseless. Courts have repeatedly dismissed RICO claims challenging purported "copayment subsidy enterprises," and have specifically rejected allegations that such "schemes" involve mail or wire fraud. *See Plumbers & Pipefitters Loc. 572*, 2014 WL 12621229, at *4-5 (dismissing RICO claim where the complaint "barely hint[ed] at the subject of the misrepresentations"); *Am. Fed'n of State, Cnty. & Mun. Emps.*, 948 F. Supp. 2d at 347-48. Presumably for that reason, Plaintiffs do not even try to

allege that Teva's copayment assistance program for patients on commercial insurance violates RICO. The allegation that Teva violated the AKS by supposedly channeling similar support payments to Medicare patients does not support a different result. As noted, p. 47, *supra*, Congress did not create a private right of action under the AKS, and it did not include AKS violations in RICO's "exhaustive" list of RICO predicate acts, *see Annulli v. Panikkar*, 200 F.3d 189, 200 (3d Cir. 1999), *overruling recognized by Kach v. Hose*, 589 F.3d 626 (3d Cir. 2009). Courts have thus unsurprisingly held that alleged violations of the AKS do not qualify as RICO predicate offenses.[19] There is no basis to circumvent Congress's choice by treating every alleged AKS violation that happened to use the mail or wires as a RICO predicate offense.

**2. Plaintiffs' Vague Allusion To The Travel Act Does Not Plausibly Allege A RICO Predicate Offense.**

Plaintiffs also make a conclusory allegation (Compl. ¶ 261) that Teva engaged in "unlawful activity" that is indictable under the Travel Act, 18 U.S.C. § 1952, a statute enacted as part of a "legislative program directed against 'organized crime,'" *Perrin v. United States*, 444 U.S. 37, 41 (1979). "[U]nlawful activity" is a defined

[19] *See Young v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 2017 U.S. Dist. LEXIS 218257, at *7 (N.D. Okla. Nov. 6, 2017); *Ill. Farmers Ins. Co. v. Mobile Diagnostic Imaging, Inc.*, 2014 WL 4104789, at *9 (D. Minn. Aug. 19, 2014); *Allen Neurosurgical Assocs., Inc. v. Lehigh Valley Health Network*, 2001 WL 41143, at *3 (E.D. Pa. Jan. 18, 2001).

term under the Act, which enumerates several discrete offenses that qualify. 18 U.S.C. § 1952(b)(i). Plaintiffs do not, however, articulate what specific "unlawful activity" is alleged, and so their pleading fails to give "fair notice" of the claim. *Twombly*, 550 U.S. at 555 (citation omitted).

In any event, the facts alleged do not support a plausible Travel Act violation under any theory. Teva obviously has not engaged in illegal gambling, drug offenses, prostitution, extortion, arson, or money laundering. 18 U.S.C. § 1952(b)(i)(2). Nor has the Complaint plausibly alleged that Teva engaged in "bribery … in violation of the laws of … the United States." An alleged offense qualifies as "bribery" under the Act only if its elements fall within the "generic" meaning of bribery as understood "at the time Congress enacted the statute in 1961." *Perrin*, 444 U.S. at 42, 49; *accord In re EpiPen Direct Purchaser Litig.*, 2022 WL 1017770, at *4 (D. Minn. Apr. 5, 2022). Generic bribery, in turn, encompasses only those payments that corrupt "relations which are recognized in a society as ***involving special trust*** [that] should be kept secure from the corrupting influence of bribery." *United States v. Ferriero*, 866 F.3d 107, 123 (3d Cir. 2017) (emphasis added and citation omitted).

An alleged violation of the AKS does not fall within this definition of bribery, as none of the AKS's elements requires a "'special trust' or other fiduciary

relationship." *EpiPen Direct Purchaser Litig.*, 2022 WL 1017770, at *5.[20] Instead, the AKS covers "***any*** remuneration," including "kickback[s]" and "rebate[s]," not just bribes, with no requirement that any payment implicate a relationship of "special trust." *See* 42 U.S.C. § 1320a-7b(b)(2) (emphasis added). Because the conduct proscribed by the AKS "is broader than generic bribery under the Travel Act," Plaintiffs cannot rely on the AKS to make out a RICO predicate offense through the Travel Act. *EpiPen Direct Purchaser Litig.*, 2022 WL 1017770, at *5-6.

Not only does an AKS violation fail to fit within the generic definition of bribery as a categorical matter, but the specific conduct alleged here also does not match the definition. The Complaint lacks ***any*** allegations related to Teva's alleged charitable contributions that plausibly suggest a relationship "involving special trust," as required for generic bribery under the Travel Act. *See Ferriero*, 866 F.3d at 123 (citation omitted). Indeed, the Complaint does not allege that Teva engaged in "bribery" of ***any*** kind, but instead refers to the alleged charitable contributions as "payments" or "kickbacks." Compl. ¶¶ 180, 182. Thus, Plaintiffs cannot establish a RICO predicate offense through the Travel Act.

**B. The Complaint Fails To Plausibly Allege Proximate Causation.**

The Complaint also fails to plausibly allege the necessary causal connection

[20] The Complaint does not identify any other offense satisfying the generic definition of bribery that Teva conceivably violated through its alleged charitable contributions.

between Plaintiffs' alleged financial injury and a RICO predicate offense. A RICO plaintiff must plausibly allege "that a RICO predicate offense … was the proximate cause" of its injury. *Hemi Grp., LLC*, 559 U.S. at 9 (citation omitted). Proximate cause in the RICO context requires "some direct relation between the injury asserted and the injurious conduct alleged." *Id*. (citation omitted). Courts look to a number of factors in assessing the directness of a causal connection, including the length of the causal chain, whether "[other] factors" contributed to the alleged injury, and whether the plaintiff is the "immediate victim[]" of the alleged RICO violation. *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 457-60 (2006). Nonetheless, the "general" rule is that proximate cause does "not [] go beyond the first step" in the causal chain. *Hemi Grp. LLC*, 559 U.S. at 10 (citation omitted).

The Complaint fails right out of the gate because it does not plausibly allege any discernable—much less plausible—causal connection between any predicate act and Plaintiffs' purported injury of purchasing additional Copaxone. Compl. ¶ 262. The Complaint fails to plausibly allege ***any*** causal chain for the alleged mail and wire fraud predicates, but simply asserts in a single sentence that someone "transmi[tted]" unidentified "untrue or incomplete statements intended to mislead health care purchasers." *Id*. ¶ 259. The Complaint does not allege that these misstatements were made ***to*** "health care purchasers." *See Plumbers & Pipefitters Loc. 572*, 2014 WL 12621229, at *4 (alleged fraud in pharmacy processing of "co-

pay subsidies" was "too 'attenuated'" from the purchasers' injury where allegedly fraudulent statements were "never transmitted" to the purchasers) (citation omitted). Nor, for that matter, does it allege that ***anyone*** relied on a specific "untrue or incomplete statement," further undermining Plaintiffs' RICO claim. *See Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. 639, 658-59 (2008) ("absence of reliance" on alleged false statement by any party "may prevent the plaintiff from establishing proximate cause."). The Complaint's allegations are even more opaque when it comes to the Travel Act. As discussed, pp. 54-55, *supra*, the Complaint does not identify a specific theory for how Teva's charitable contributions violated the Travel Act. Even if Plaintiffs mean to bootstrap an AKS violation into a Travel Act claim (which they cannot do, *see* pp. 55-56, *supra*), the Complaint does not allege facts tying such a violation to their alleged injury.

In any event, any possible connection between the alleged predicate acts and Plaintiffs' increased purchases of Copaxone is far too remote. At bottom, Plaintiffs allege that Teva was part of a RICO enterprise to circumvent anti-kickback restrictions applicable to Medicare patients, which allowed Teva to offer copay support for Copaxone purchases, which, in turn, persuaded patients to choose Copaxone over a generic alternative and "induce[d]" additional prescriptions for Copaxone, culminating in Plaintiffs having to purchase some additional amount of Copaxone "despite the availability of more cost-effective generic Copaxone."

Compl. ¶¶ 254-57, 262. This theory that Plaintiffs overpaid for Copaxone because Teva supposedly violated anti-kickback rules intended to protect the federal fisc goes well beyond the "first step" of the causal chain, and therefore "cannot meet RICO's direct relationship requirement." *Hemi Grp. LLC*, 559 U.S. at 10; *see Anza*, 547 U.S. at 457-58 (proximate cause not satisfied where the defendant allegedly defrauded the state tax authority by failing to collect sales tax and then lowered its prices, to the detriment of competitors like the plaintiff).

The causal chain is not only too long, but it is broken by independent acts of third parties. The alleged provision of a copayment subsidy to Medicare patients does not automatically result in increased Copaxone sales. Rather, as alleged, the subsidies merely eliminated an economic disincentive for patients to stay on Copaxone by closing the difference in out-of-pocket expense for patients between brand and generic. Compl. ¶¶ 170-72. Not only must that price incentive result in a patient choosing Copaxone, but the doctor must exercise his "independent medical judgment" to decide whether to write a DAW prescription for Copaxone—and keep the patient on the Copaxone regimen—or allow generic substitution. *District 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 524, 525 (D.N.J. 2011). The exercise of that independent medical judgment is an intervening cause

that further undermines Plaintiffs' theory of proximate causation.[21]

This "discontinuity between the [alleged] RICO violation and the asserted injury" is compounded by Plaintiffs' kitchen-sink theory of antitrust liability. *Anza*, 547 U.S. at 459. The Complaint identifies numerous factors that allegedly contributed to increased brand Copaxone sales—and thus Plaintiffs' alleged injury—that have nothing to do with the purported RICO enterprise, such as the success of Teva's DAW campaign and the discounts it offered to PBMs and specialty pharmacies. *E.g.*, Compl. ¶¶ 145, 168. Indeed, Plaintiffs specifically allege that it is the "combined effect" of Teva's alleged conduct that has allowed Teva to maintain significant market share after generic entry. *Id.* ¶ 188. As a result, Plaintiffs effectively concede that their purported injury "could have resulted from factors other than" Teva's alleged RICO predicate acts, which will in turn make it exceptionally difficult to ascertain "what portion of [Plaintiffs' alleged overcharges] were the product of" the alleged RICO predicate acts, as opposed to other factors. *Anza*, 547 U.S. at 458-59. These concerns further "illustrate why [Plaintiffs'] alleged injury was not the direct result of a RICO violation." *Id.* at 459; *see also*

[21] *See Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 485 (D.N.J. 1998) (doctors' decisions to "prescribe [one drug] instead of [another]" was an "intervening act[]" that undermined proximate causation); *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 577 (7th Cir. 2017) (rejecting, on a motion to dismiss, proximate causation in a case alleging improper drug promotion because it would not be workable to "[d]isentangl[e] the promotions" from "other influences on physicians' prescribing practices").

*Longmont United Hosp. v. Saint Barnabas Corp.*, 305 F. App'x 892, 896 (3d Cir. 2009) (affirming dismissal of RICO claim where an intermediary in the causal chain made it "nearly impossible to ascertain the amount of [the plaintiff's] damages attributable to [the defendant's wrongdoing]").

Finally, the lack of a "direct causal connection" between Plaintiffs' alleged injury and the purported RICO violations is confirmed by the fact that Plaintiffs are not the "direct victim[s]" of Teva's alleged RICO enterprise. *Anza*, 547 U.S. at 458, 460. As discussed, pp. 54, 55-56, *supra*, Plaintiffs' RICO claim appears to be based on Teva's alleged evasion of AKS restrictions for government programs—a point illustrated by the telling omission of any reference to commercial copay assistance from the Complaint's RICO count. *See* Compl. ¶¶ 252-63. But the AKS "was enacted to 'protect the Medicare and Medicaid programs from increased costs and abusive practices.'" *United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015) (citation omitted). Violations of the AKS are thus wrongs "perpetrated upon the United States government," *Baglio v. Baska*, 940 F. Supp. 819, 834 (W.D. Pa. 1996), *aff'd*, 116 F.3d 467 (3d Cir. 1997), and only the federal government is authorized to enforce that law, p. 47, *supra*. Plaintiffs, mere indirect victims of any putative AKS violation, should not be allowed to use RICO to privately enforce the AKS based on the theory that alleged kickbacks impacting Medicare had a downstream impact on drug purchasers. *See Hemi Grp. LLC*, 559 U.S. at 11-12 (no proximate causation

where there are "better situated plaintiffs" who "have an incentive to sue").

### C. The RICO Claim Is Untimely.

Plaintiffs' RICO claim is also untimely. Civil RICO claims are subject to a four-year limitations period, so any RICO claim that accrued on or before March 8, 2018 is time barred. *See Agency Holding Corp. v. Malley-Duff & Assocs., Inc.*, 483 U.S. 143, 156 (1987). A RICO claim accrues when "the plaintiffs knew or should have known of their injury" and the "source of the injury." *Forbes v. Eagleson*, 228 F.3d 471, 484, 485 (3d Cir. 2000). A plaintiff "should have known" of its injury when it "ha[s] sufficient information of possible wrongdoing to place [it] on 'inquiry notice' … of culpable conduct." *Cetel v. Kirwan Fin. Grp., Inc.*, 460 F.3d 494, 507 (3d Cir. 2006) (citation omitted). Once that standard is met, the burden "shifts … to plaintiffs to show that … they exercised reasonable diligence" in attempting to uncover the relevant facts. *Id*.

As discussed, Plaintiffs' RICO claim is built off the DOJ's allegations that Teva's contributions to charitable foundations, including to the Chronic Disease Fund ("CDF"), violated the AKS. Compl. ¶¶ 175-82, 252-63. Plaintiffs were on at least inquiry notice of this claim well before March 2018. Beginning as early as 2005, and continuing over the next decade, news organizations documented the practice of drug companies donating to charities that provide copay support to Medicare patients, and raised questions about whether such donations implicate anti-

kickback prohibitions. *See* Declaration of Liza M. Walsh, Ex. 1-3.[22] Then, in 2016, it was reported that federal agencies had opened investigations into whether drug companies' donations to certain charities—including CDF—violated the AKS. *Id*., Ex. 4-5. Subsequently, in 2017, reporting revealed that these investigations also targeted the drug company donors themselves, including Teva. For example, a March 2017 article reported that Teva had been served with a summons from the Internal Revenue Service ("IRS") "as part of an investigation into whether [CDF] had conferred impermissible benefits on drugmakers who provided donations." *Id*., Ex. 6; *see also id*., Ex. 7 (reporting judicial approval of IRS summons to Teva in connection with investigation of whether CDF made "impermissible benefits to pharmaceutical companies that had donated to the charity"). Then, in May 2017, Teva's SEC filings disclosed that "[o]n March 21, 2017, Teva received a subpoena from the U.S. Attorney's office in Boston, Massachusetts requesting documents related to Teva's donations to patient assistance programs." *Id*., Ex. 8 at 34. Later that summer, multiple news organizations reported that the DOJ and the IRS were investigating CDF for possible AKS violations, and that Teva (and other drug

[22] The Court can take judicial notice of materials in the public record, such as newspaper articles and SEC filings, for purposes of resolving a motion to dismiss on statute of limitations grounds. *See Benak ex rel. All. Premier Growth Fund v. All. Cap. Mgmt. L.P.*, 435 F.3d 396, 401 n.15 (3d Cir. 2006) (approving judicial notice of newspaper articles as part of "inquiry notice" analysis); *FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147, 151 n.5 (3d Cir. 2019) (taking judicial notice of public SEC filings).

companies) had received subpoenas. *Id.*, Ex. 9 (discussing DOJ "investigation of drug companies' activities under … the anti-kickback statute," that "the IRS is investigating not only [CDF] but its donors," and noting that Teva was the recipient of an IRS summons); *id.*, Ex. 10 (discussing IRS summons on Teva in relation to its "probing whether [CDF] wrongly gave a benefit to its pharmaceutical company donors by returning most of the money they donated as payments for drugs they make").

These public documents put Plaintiffs on notice of both their alleged "injury" and the "source of the injury" well before March 2018. *Forbes*, 228 F.3d at 484, 485; *see also Hughes v. Vanderbilt Univ.*, 215 F.3d 543, 548 (6th Cir. 2000) (finding inquiry notice based on news reports); *Weiss v. Bank of Am. Corp.*, 153 F. Supp. 3d 831, 839 (W.D. Pa. 2015) (standard for inquiry notice "assumes knowledge of [publicly] available news articles"). Not only did public reports describe concerns that drug companies' donations to charitable foundations running copay-support programs may implicate antikickback laws, but they identified the CDF—one of the charities in the alleged RICO enterprise, Compl. ¶¶ 175, 255—as a subject of the government investigations. And public reporting further revealed that Teva had been swept into the investigation of the CDF. Collectively, this information was more than sufficient to place Plaintiffs on notice of the conduct they now challenge long before the March 8, 2018 accrual date. Plaintiffs have not, however, "pleaded

any facts showing that [they] exercised reasonable due diligence in attempting to uncover the relevant facts in connection with [the] RICO claim." *Love v. City of New Brunswick*, 2018 WL 429247, at *13 (D.N.J. Jan. 16, 2018) (emphasis omitted). Therefore, their claim accrued before March 8, 2018 and is time-barred.

## III. Plaintiffs Cannot Recover Damages For Alleged Conduct That Occurred Outside The Limitations Period.

Even if any of Plaintiffs' claims survive dismissal, Plaintiffs cannot rely on a theory of fraudulent concealment to recover damages for alleged injuries incurred outside the four-year limitations period applicable to Plaintiffs' Sherman Act and RICO claims. *See* Compl. ¶ 222; pp. 39, 62, *supra*. Allegations of fraudulent concealment are subject to Rule 9(b)'s heightened pleading standard. *In re Magnesium Oxide Antitrust Litig.*, 2011 WL 5008090, at *20 (D.N.J. Oct. 20, 2011). To establish fraudulent concealment, a plaintiff must adequately allege (1) "an affirmative act of concealment," which (2) "misleads … the plaintiff[]," and that (3) the plaintiff "exercised due diligence in investigating his cause of action." *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1178-79 (3d Cir. 1993) (antitrust claim); *see Mathews v. Kidder, Peabody & Co., Inc.*, 260 F.3d 239, 256 (3d Cir. 2001) (same for RICO claim). Plaintiffs' allegations fail at each step.[23]

[23] Plaintiffs' antitrust claims are subject to "a pure injury accrual rule," meaning the statute of limitations "begins to run when a defendant commits an act that injures a plaintiff's business"—not when the plaintiff discovers or should have discovered the injury. *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 188 (1997) (citation omitted). In

### A. Nearly All Of Plaintiffs' Allegations Describe Passive, Not Active, Concealment.

Tolling under a theory of fraudulent concealment is available only where the defendant "engaged in ***affirmative*** acts of concealment designed to mislead plaintiffs about a fact supporting their" claim. *Forbes*, 228 F.3d at 487 (emphasis added). Because the doctrine requires "***active*** misleading on the part of the defendant," allegations that the defendant merely "concealed" (*i.e.*, failed to disclose) a fact are insufficient. *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1391 n.10 (3d Cir. 1994), *overruled on other grounds by Rotkiske v. Klemm*, 890 F.3d 422, 427-28 (3d Cir. 2018); *see also In re Mercedes-Benz Anti-Trust Litig.*, 157 F. Supp. 2d 355, 368 (D.N.J. 2001) ("Fraudulent concealment cases stress that plaintiff must show 'active misleading' by defendants[.]") (citation omitted).

Yet the Complaint relies heavily on allegations that Teva ***passively*** concealed certain aspects of its purported "scheme." Compl. ¶¶ 222-31. For example, Plaintiffs allege that "Teva took steps to keep … secret" its alleged exclusionary agreements with PBMs and specialty pharmacies. *Id.* ¶ 223. Those allegations are not only conclusory, but are precisely the type of passive-conduct allegations that

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other words, a plaintiff need not "actually discover its antitrust claims before the statute of limitations begins to run." *Hexcel Corp. v. Ineos Polymers, Inc.*, 681 F.3d 1055, 1060 (9th Cir. 2012). As discussed above, Plaintiffs' RICO claims accrued when Plaintiffs knew or reasonably should have known about their alleged injury and its source. *See* p. 62, *supra*.

courts have rejected as insufficient. *See, e.g.*, *Oshiver*, 38 F.3d at 1391 n.10; *Conmar Corp. v. Mitsui & Co. (U.S.A.), Inc.*, 858 F.2d 499, 505 (9th Cir. 1988) ("Passive concealment of information is not enough to toll the statute of limitations … unless the defendant had a fiduciary duty to disclose the information to the plaintiff.").[24] Plaintiffs' focus on Teva's alleged "***private*** actions [and] communications" thus misses the mark. *Reveal Chat Holdco, LLC v. Facebook, Inc.*, 471 F. Supp. 3d 981, 993 (N.D. Cal. July 8, 2020). Likewise, Plaintiffs cannot rely on allegations that they "could not have known" of certain alleged conduct until the House Report was released, Compl. ¶ 224, because Plaintiffs do not tie those allegations to any steps (affirmative or otherwise) taken by Teva to mislead anyone.

Finally, the Complaint alleges that Teva's scheme was "inherently self-concealing because … its disclosure would have exposed" Teva to liability. Compl. ¶ 229. That charge is unsupported and ignores that many aspects of Teva's purported "scheme" were public facing, such as its launch of Copaxone 40 mg and its DAW messaging. *See id*. ¶¶ 131, 162-66. Moreover, it "would eviscerate the

[24] Even assuming Plaintiffs could rely on allegations of passive concealment, Plaintiffs' allegations are lacking. The Complaint alleges that Teva took two steps to conceal the alleged agreements: (1) unidentified "senior Teva executives" informed other Teva employees that the agreements were "confidential" and should not be shared; and (2) internal communications regarding the contracts were labeled "DO NOT COPY. DO NOT DISTRIBUTE." Compl. ¶ 223. In other words, Plaintiffs allege nothing more than that Teva adopted routine measures to keep its internal business documents confidential.

very concept of a limitations period," *Schmidt v. Skolas*, 770 F.3d 241, 255 (3d Cir. 2014), if that period could be tolled any time a plaintiff alleges that the defendants knew that disclosure of their (supposedly unlawful) conduct could expose them to legal consequences.

### B. To The Extent Plaintiffs Allege Active Concealment, Their Allegations Are Insufficient.

Beyond faulting Teva for nondisclosure, the Complaint alleges that Teva provided "pretextual justifications" for its Copaxone pricing by referencing unidentified statements regarding Teva's research and development efforts and a set of October 2016 talking points explaining that Copaxone 40 mg "offer[ed] a strong value proposition" compared to the generic 20 mg product. Compl. ¶ 225. Even if these allegations could be construed as examples of affirmative misstatements, rather than mere passive concealment, they provide no basis for tolling.

First, these allegations flunk Rule 9(b)'s pleading standard. As to Teva's research and development efforts, "Plaintiffs do not state who made these statements, to whom they were made, when they were made, or what was said." *In re Aspartame Antitrust Litig.*, 2007 WL 5215231, at *5 (E.D. Pa. Jan. 18, 2007). Likewise, as to the talking points, Plaintiffs fail to identify when, how, or by whom this information was shared with the public—all information available to Plaintiffs. *See id.* ("statements allegedly made to the public" are not subject to a relaxed standard under Rule 9(b)).

Second, the manner in which Teva allegedly characterized its conduct does not qualify as concealment when the facts surrounding the conduct are publicly known. *See In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 748 (E.D. Pa. Sept. 5, 2014) (rejecting fraudulent concealment allegations on a motion to dismiss where the plaintiff alleged that the defendants had "falsely characterized the[ir] settlement agreements as procompetitive" and "refused to disclose certain details," because key settlement terms had been publicly disclosed). Thus, allegations that Teva concealed its true "motivat[ion]" for launching a 40 mg product and gave "pretextual justifications for its Copaxone pricing," Compl. ¶¶ 224-25, are legally insufficient: As direct purchasers, Plaintiffs were well-aware of Teva's product offerings and the prices it charged, and so were fully capable of independently assessing the merits of Teva's alleged statements.

Third, Plaintiffs fail to allege that they "relied on" any "act of concealment," *In re Magnesium Oxide*, 2011 WL 5008090, at *23, which requires, at a minimum, that alleged fraudulent acts "were directed toward [Plaintiffs] and that [Plaintiffs] were aware" of them, *In re Magnesium Oxide Antitrust Litig.*, 2012 WL 1150123, at *7-8 (D.N.J. Apr. 5, 2012). Plaintiffs do not even allege that they were aware of any alleged misstatements, let alone that they relied on them in deciding not to bring suit sooner. *See In re Magnesium Oxide*, 2011 WL 5008090, at *23 (dismissing

plaintiffs' fraudulent-concealment claim where they made "no allegations that they were misled by Defendants' concealment of the alleged conspiracy").

### C. Plaintiffs Fail To Allege That They Were Reasonably Diligent In Uncovering Their Claims.

Finally, Plaintiffs have "fail[ed] to allege any due diligence," and are therefore "virtually foreclosed from invoking the fraudulent concealment doctrine." *Niaspan*, 42 F. Supp. 3d at 749 (citation omitted). Plaintiffs merely allege that, because "Teva was operating in a competitive market," a reasonable person would not have "suspect[ed] that Teva was engaged in an overarching monopolization scheme." Compl. ¶ 230. However, courts have "reject[ed]" efforts to avoid the due-diligence requirement "by alleging that [a] conspiracy was 'self-concealing,'" *Niaspan*, 42 F. Supp. 3d at 749 n.8 (citation omitted), or that "simply … because Plaintiffs say they did not know *x*, *x* must have been so cleverly concealed that they never could have known *x*," *In re Processed Egg Prods. Antitrust Litig.*, 2011 WL 5980001, at *14 (E.D. Pa. Nov. 30, 2011).

Rather, where, as here, a plaintiff had "sources of information sufficient to place it on inquiry notice" of the facts underlying its claims, the plaintiff is charged with the responsibility to investigate those claims. *Prudential Ins. Co. of Am. v. U.S. Gypsum Co.*, 359 F.3d 226, 238 (3d Cir. 2004). "[I]nquiry notice should not await the dawn of complete awareness. Full knowledge often awaits discovery, and the very notion of 'inquiry notice' implies something less than that." *Go Computer, Inc.*

*v. Microsoft Corp.*, 508 F.3d 170, 178 (4th Cir. 2007) (citation and quotation marks omitted); *see also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 224 (E.D.N.Y. 2003) (holding that even if the defendants had "concealed their actions, disclosed facts in the public domain would have been more than adequate to raise [the plaintiffs'] suspicions as to their claim of injury"). "It is enough that the plaintiff should have been alerted to facts that, following duly diligent inquiry, could have advised it of its claim." *Hexcel Corp.*, 681 F.3d at 1060 (citation and quotation marks omitted).

Here, the Complaint identifies a series of allegations that should have put Plaintiffs on notice of the need to investigate their claims. Plaintiffs allege, for example, that "[a]lthough a brand manufacturer's market share typically falls to 10% or less within one year of generic entry, Teva's exclusionary scheme enabled it to maintain a majority of the Copaxone market for years following generic entry." Compl. ¶ 119. This alleged market imbalance would have been clear to Plaintiffs well before they filed the Complaint. Plaintiffs likewise allege that "Teva manipulated pricing," *id.* ¶ 133, but as direct purchasers, they necessarily were on notice of Teva's pricing practices for both dosages of Copaxone. Moreover, as discussed, pp. 62-64, *supra*, numerous publicly available sources put Plaintiffs on inquiry notice of Teva's alleged charitable donations for Medicare patient co-pay support. Indeed, Plaintiffs acknowledge that this "aspect" of Teva's alleged scheme

"became public prior to the publication" of the House Report, as they must, since "the DOJ announced that it had entered into a settlement" with The Assistance Fund—the second charity in Plaintiffs' alleged RICO scheme, Compl. ¶¶ 175, 255—in November 2019. *Id*. ¶ 227.

Combined, these allegations put Plaintiffs on notice of the need to investigate their claims, but the Complaint contains ***no*** allegations that Plaintiffs undertook any investigation. Rather, Plaintiffs merely assert in conclusory fashion that any investigation would have been unsuccessful. Compl. ¶ 222. Plaintiffs' thus fail to plausibly allege that the statute of limitations can be tolled as the result of fraudulent concealment.

## CONCLUSION

The Court should dismiss the Complaint with prejudice.

Respectfully submitted,

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